Serious complications associated with spinal and epidural anaesthesia in Finland from 2000 to 2009

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Background: Analyses of closed claims provide insight into the characteristics of rare complications. Serious complications related to spinal and epidural blocks are relatively rare. In Finland, all malpractice cases are primarily handled by the Patient Insurance Centre (PIC) within a 'no-fault scheme'.

Methods: All claims attributed to central neuraxial blocks and settled by the PIC during the period, 2000–2009 were analysed. The number of spinal and epidural procedures performed during this time was estimated based on a questionnaire sent to all surgical hospitals in Finland in 2009, surveying the numbers and types of neuraxial blocks carried out in 2008.

Results: During the study period, 216 closed claims were flagged with spinal or epidural blocks. In 41 of 216 instances, the neuraxial block was apparently responsible for a serious (fatal or critical or lasting >1 year) complication. These included six fatalities and 13 epidural haematoma (two in conjunction with fondaparinux, three with excessive doses of low molecular weight heparins, six where present guidelines were not observed). Fatalities occurred in 1:775,000 spinals for surgery, 1:62,000 in epidurals for surgery or acute pain relief, 1:144,000 epidurals for labour. The incidence of neuraxial haematoma after spinal block was 1:775,000, that for epidural block 1:26,400, and in the case of combined spinal and epidural, 1:17,800. Irrespective of the method of neuraxial technique, the majority of patients suffering serious complications were the elderly having comorbidities.

Conclusions: In this closed claims analysis, major problems related to neuraxial blocks were rare. Epidural or a combined spinal and epidural technique resulted in more complications than did spinal procedure.

Accepted for publication 9 December 2012

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Spinal and epidural blocks are highly accepted techniques with a rather low incidence of serious complications. Albeit rare, it is difficult to survey the presence of all these problems. Collecting complications from a single hospital requires a long time period, while retrospective reviews of such complications may underestimate the rate. A large workload is needed to provide more comprehensive surveys. National projects which record complications and survey the incidents in a real-time fashion yield more reliable information. Another way to calculate the rates for rare complications is based on data from records of claims. Such was the approach by Aromaa et al. which estimated the incidence of complications of neuraxial techniques adapted from Finnish patient insurance claims. In Finland, the Patient Injury Act (1987) offers a 'no-fault scheme' which directs patients who feel that they have suffered a complication as a consequence of their medical treatment, filing for financial compensation from the Patient Insurance Center (PIC). This is rather than taking legal action against the health-care providers. Eventually, the PIC becomes a source of information for national statistics and for developing possible preventive measures.

Studies based on self-reporting systems need to be updated in order to ascertain the direction of development of care and potential new risk factors. Therefore, comparable to the earlier study, we searched the PIC archives from 2000–2009 for all closed claims that resulted from spinal and epidural techniques. We were, for example, interested to learn whether the incidence of neuraxial haematoma had changed with the introduction of new thrombosis prophylaxis drugs in accordance to guidelines for their use.
Methods

With permission of The Ministry of Social Affairs and Health obtained, PIC archives from 2000 to 2009 were examined for anaesthesia-related closed claims using a computer-based search tool with particular attention given to situations involving central neuraxial block. The authors (MP, UA, JF) examining the archives took care to ensure the anonymity of the individuals involved. Collected details were entered into a separate database without names of patients, hospital personnel, institution, or locations.

A typical file consisted of the application, relevant hospital and anaesthesia records, remarks by the anaesthetist and others connected with the patient, together with reviews of external experts (anaesthesiologists). We recorded data pertaining to the patients' pre-operative status, details of neuraxial block, possible medication which could affect blood coagulation, and nature and outcome of the adverse effects. Diagnosis of the complication was obtained from the files. Complications were divided into serious and minor events. A serious result was defined as being potentially life-threatening and/or remaining in excess of one year.

In order to obtain an approximate denominator, i.e., the number of spinal and epidural blocks performed during the survey period, a questionnaire (Appendix S1) was sent to chief anaesthesiologists in hospitals in Finland which provide surgical and/or obstetric units. The survey was made in 2009 based on information regarding the number of procedures made during 2008.

Results

Data overview

During 2000–2009, the PIC annually received some 8000 claims of which approximately one-third had resulted in compensation paid. The yearly cost amounted to about 30 million euros.

The number of all anaesthesia-related claims was less than one percent. During the 10-year study period, a total of 216 claims were found to involve spinal or epidural block. Of these, 129 claims were excluded either because it was judged that neuraxial block would not be responsible for the claimed conditions (e.g., pre-existing pain involving the spine, migraine, or herniated lumbar disk) or the complaint was of lesser importance (e.g., pain which occurred at time of the puncture).

Of the remaining 87 situations, 46 were classified as being minor, and 41 were serious or permanent (> 1 year) ones (Tables 1 and 2).

Out of these 41 cases, in 17 instances, the PIC decided that at some point the patient treatment was below the level of the care required from an experienced health-care professional. This number includes five of six fatalities and five of 13 haematomata.

Forty-three of the 45 hospitals returned the questionnaires. Based on that information, we extrapolated the approximate number of neuraxial blocks performed nationwide within 2008 and the 10-year study period (Table 3).

Fatalities

The serious complications are shown in Tables 1 and 2. Six patients had a fatal consequence; two of these resulted from errors in medication, one was related total spinal anaesthesia, and another due to bacterial infection. The fifth fatality occurred some 4 months after an epidural haematoma, while the sixth died 7 months after suffering nerve root damage. The details of these patients are as follows:

Case 27. Male, 67 years old, 184 cm, 118 kg, underwent laparoscopic cholecystectomy under general anaesthesia. Leakage of bile, however, necessitated re-operation. Epidural analgesia for pain relief was commenced. After this surgery, he was followed up in the intensive care unit, and then moved back to his ward. There, the rate of the epidural infusion (bupivacaine 1 mg/ml with fentanyl 4 µg/ml) was started at 88 ml/h, rather than at the designated 8 ml/h. After 25 min, the patient suffered circulatory collapse and was resuscitated. He, however, had experienced brain damage and died 2 weeks later.

Case 28. Male, 83 years old, 176 cm, 80 kg, with generalised atherosclerosis and ischemia of the lower limbs. Epidural analgesia with fentanyl 5 µg/ml in ropivacaine 1 mg/ml (mixture of ropivacaine 2 mg/ml and sodium chloride) was started. The syringe was changed at 04:30 hours. (this particular drug solution was prepared by a nurse) in the ward. Later that morning, he developed tachycardia, cardiac arrhythmias, and complained of pain in the right arm. Acute myocardial infarction was diagnosed, and the patient died at 11:45 hours. During that same day, a second patient with epidural analgesia in that same ward developed similar symptoms. Only then it became evident that because of human error, the ward’s medicine cabinet contained ampoules of potassium chloride in place of isotonic saline. Postmortem cerebrospinal fluid
### Table 1

<table>
<thead>
<tr>
<th>Case no.</th>
<th>Gender (F/M)</th>
<th>Co-morbidities</th>
<th>Procedure</th>
<th>Anaesthesia</th>
<th>Comments</th>
<th>Thromboprophylaxis</th>
<th>Present guidelines followed</th>
<th>Spinal stenosis</th>
<th>Symptoms and diagnostics</th>
<th>Surgical evacuation, time between onset of symptoms and surgical procedure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>E</td>
<td>M, 48, 27.4 DM, HA, depression</td>
<td>Laparotomy (colorectal cancer)</td>
<td>GA, then epidural catheter for analgesia, L2-3</td>
<td>Uneventful puncture, postoperative pain at site of surgery, manipulation of epidural catheter&lt;br&gt;Unventful anaesthesia, normal recovery from spinal&lt;br&gt;puncture</td>
<td>Dalteparin 2500 IU daily</td>
<td>Yes</td>
<td>No</td>
<td>Sensory and motor block, 3 days after puncture and during epidural infusion</td>
<td>No (after consulting neurosurgeon) Permanent paraparesis, incontinence</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>E</td>
<td>F, 67, 26.2 Ribomycelia</td>
<td>Knee arthroscopy</td>
<td>Spinal</td>
<td>NA</td>
<td>Yes</td>
<td>Symptoms after recovery of spinal pain, sensory, motor block, 10 h after the spinal puncture</td>
<td>Yes, 16 h</td>
<td>Recovered</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>E</td>
<td>M, 85, unknown MCC, CI, HA</td>
<td>Chorionic pain</td>
<td>Single epidural [for pain relief, L1-2]</td>
<td>Epidural anaesthesia up to T10, recovered</td>
<td>None</td>
<td>NA</td>
<td>Yes</td>
<td>Sensory and motor block developed day 1 after epidural puncture</td>
<td>No (due to patient’s condition) Paraplegic, death at 3.5 months</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>E</td>
<td>F, 86, 28.6 DM, MCC, FA</td>
<td>THA</td>
<td>CSE L2-3</td>
<td>Not recorded</td>
<td>Enoxaparin 40 mg daily post-operatively</td>
<td>Yes</td>
<td>Yes</td>
<td>Pain, motor block on 1st postoperative morning; MRI in evening</td>
<td>No Paraplegia</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>E</td>
<td>F, 86, 30.0 DM, MCC, HA, cardiac pacemaker</td>
<td>Vascular surgery</td>
<td>Epidural catheter, L3-4</td>
<td>Catheter removed on 2nd POD</td>
<td>Dalteparin 2500 IU twice daily</td>
<td>No</td>
<td>(High dalteparin dose)</td>
<td>Motor block and paraparesis 3rd POD, MRI on 4th POD; haematoma</td>
<td>No Paraplegia</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>E</td>
<td>F, 80, 23.6 Cystitis due to tuberculosis</td>
<td>TKA</td>
<td>CSE L2-3</td>
<td>Difficult puncture, several attempts</td>
<td>Fondaparinux 2.5 mg daily</td>
<td>No</td>
<td>(Catheter removed 16 h after fondaparinux)</td>
<td>Back pain 3rd POD, epidural catheter removed, weakness in legs 4th POD; paraparesis 5th POD, followed by CT</td>
<td>Yes, 18 h Partial recovery, incontinence, paraparesis</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>E</td>
<td>F, 66, 23.9 HA, CI</td>
<td>TKA</td>
<td>CSE spin L3-4, epid L4-5</td>
<td>Not recorded</td>
<td>Enoxaparin 40 mg daily</td>
<td>No (Catheter removed early morning; &lt; 12 h after enoxaparin dose)</td>
<td>No</td>
<td>Blood in the epidural catheter 2nd POD, catheter removed, paraparesis 3rd POD and worsening paraparesis, MRI</td>
<td>Yes, &gt; 24 h Incontinent, needs walking frame</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>E</td>
<td>F, 79, 26.1 MCC, st post myocardial infarction, intracranial bleeding</td>
<td>TKA</td>
<td>Epidural catheter</td>
<td>Difficult puncture, spinal failed, but epidural catheter placed</td>
<td>Fondaparinux 2.5 mg daily</td>
<td>No</td>
<td>(Catheter removed &lt; 20 h after fondaparinux)</td>
<td>Epidural catheter removed 2nd POD, cauda equina symptoms 3rd POD, MRI</td>
<td>Yes, &gt; 24 h Walks but incontinent</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>E</td>
<td>F, 80, unknown DM, MCC, CI and kidney insufficiency</td>
<td>Laparotomy (intestinal occlusion)</td>
<td>GA, epidural catheter Th12-L1</td>
<td>Not recorded</td>
<td>Enoxaparin 40 mg daily</td>
<td>Yes</td>
<td>No</td>
<td>Epidural continued, paraparesis on 7th POD, MRI</td>
<td>Yes, 4 h Paraplegia</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>SD</td>
<td>F, 83, 23.4 FA, HA, MCC</td>
<td>Laparotomy cancer caecum</td>
<td>GA, epidural catheter, Th11-12 (dural tap)</td>
<td>Dural tap Th10-11, Th11-12</td>
<td>Enoxaparin 60 mg daily</td>
<td>No</td>
<td>(High enoxaparin dose)</td>
<td>Pain at surgical site in spite of epidural, paraplegia MRI of 3rd POD, MRI: subdural haematoma</td>
<td>Yes, 12 h Paraplegia</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>SD</td>
<td>M, 54, 23.5 Asthma bronchiale, diverticulitis</td>
<td>Abdominal aneuryism, elective surgery</td>
<td>GA, epidural catheter Th12-L1</td>
<td>Not recorded</td>
<td>None</td>
<td>NA</td>
<td>No</td>
<td>Pain and paresis, MRI prominent subdural haematoma</td>
<td>No Paraplegia</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>SA</td>
<td>F, 70, 32.5 Cardiac arrhythmias</td>
<td>TKA</td>
<td>CSE attempt</td>
<td>Blood from the needle at two spinal attempts (3.4 and L2-3), therefore only epidural catheter and GA needed</td>
<td>Enoxaparin 40 mg daily 12.5 h</td>
<td>Yes</td>
<td>No</td>
<td>Blood from the lumbar puncture site, sensory loss, MRI: subdural haematoma</td>
<td>Yes, &gt; 24 h after puncture Permanent paraparesis</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>SA</td>
<td>M, 58, 24.9 ASO, DM renal insufficiency (haemodialysis)</td>
<td>Vascular surgery</td>
<td>CSE</td>
<td>Difficult epidural puncture – 3 h after last enoxaparin dose</td>
<td>Enoxaparin 40 mg twice daily</td>
<td>No</td>
<td>(High enoxaparin dose, time of puncture related to enoxaparin dose)</td>
<td>Back pain 3 days after puncture, MRI: suspicion of subdural haematoma on 9th day, surgical intervention on 6th day</td>
<td>Yes, &gt; 24 h, only subdural bleeding Cauda equina syndrome, impotency</td>
<td></td>
</tr>
</tbody>
</table>

**Table Notes:**
- E: epidural; SD: subdural; SA: subarachnoid haematoma; BMI: body mass index; HA: hypertension; DM: diabetes; MCC: coronary disease; CI: cardiac insufficiency; FA: atrial fibrillation; ASO: Arteriosclerosis; GA: general anaesthesia; CSE: combined spinal and epidural; THA: total hip arthroplasty; TKA: Total knee arthroplasty; MRI: magnetic resonance imaging; CT: computed tomography; POD: postoperative day; NA: not announced or not applicable.
### Table 2

**Serious complications excluding haematomas.**

<table>
<thead>
<tr>
<th>Case no</th>
<th>Gender (F/M), age (yrs)</th>
<th>Comorbidities</th>
<th>Diagnosis or surgery</th>
<th>Anaesthesia</th>
<th>Complication</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.</td>
<td>F, 62</td>
<td>HA</td>
<td>Knee arthroscopy</td>
<td>Spinal</td>
<td>Cerebral and spinal abscesses</td>
<td>Death</td>
</tr>
<tr>
<td>15.</td>
<td>F, 77</td>
<td>COPD, MCC, CI</td>
<td>Abdominal surgery</td>
<td>GA and epidural catheter (9 days)</td>
<td>Epidural abscess</td>
<td>Conservative, recovered</td>
</tr>
<tr>
<td>16.</td>
<td>F, 47</td>
<td>Asthma</td>
<td>Pain; hemiated lumbar disk</td>
<td>Several single epidurals</td>
<td>Epidural abscess</td>
<td>Operation, recovery</td>
</tr>
<tr>
<td>17.</td>
<td>M, 80</td>
<td>HA, FA</td>
<td>Multiple traumata</td>
<td>Epidural analgesia (&gt; 2 weeks)</td>
<td>Epidural abscess</td>
<td>Operation, recovering</td>
</tr>
<tr>
<td>18.</td>
<td>F, 58</td>
<td>DM, HA</td>
<td>Total hip arthroplasty</td>
<td>CSE (epidural 4 days)</td>
<td>Epidural abscess</td>
<td>Conservative, Recovery</td>
</tr>
<tr>
<td>19.</td>
<td>F, 47</td>
<td>No</td>
<td>Knee ligament surgery</td>
<td>Spinal</td>
<td>Meningitis</td>
<td>Recovery</td>
</tr>
<tr>
<td>20.</td>
<td>M, 34</td>
<td>No</td>
<td>Knee arthroscopy</td>
<td>Spinal</td>
<td>Meningitis</td>
<td>Recovery</td>
</tr>
<tr>
<td>22.</td>
<td>M, 52</td>
<td>No</td>
<td>Knee arthroscopy</td>
<td>Spinal</td>
<td>Meningitis</td>
<td>Recovery</td>
</tr>
<tr>
<td>23.</td>
<td>M, 46</td>
<td>No</td>
<td>Chronic pain</td>
<td>Epidural (&gt; 2 weeks)</td>
<td>Meningitis</td>
<td>Recovery</td>
</tr>
<tr>
<td>25.</td>
<td>F, 42</td>
<td>No</td>
<td>Knee arthroscopy</td>
<td>Spinal</td>
<td>Meningitis</td>
<td>Recovery</td>
</tr>
<tr>
<td>26.</td>
<td>M, 33</td>
<td>No</td>
<td>Chronic pain</td>
<td>Epidural catheter (&gt; 2 weeks)</td>
<td>Sepsis</td>
<td>Recovery</td>
</tr>
<tr>
<td>27.</td>
<td>M, 67</td>
<td>DM, CI</td>
<td>Cholecystectomy</td>
<td>GA and epidural analgesia</td>
<td>Epidural drug overdose</td>
<td>Death</td>
</tr>
<tr>
<td>28.</td>
<td>M, 83</td>
<td>MCC, CI</td>
<td>Ischemia: lower extremities</td>
<td>Epidural analgesia</td>
<td>Wrong drug</td>
<td>Death</td>
</tr>
<tr>
<td>29.</td>
<td>F, 20</td>
<td>No</td>
<td>Labour pain</td>
<td>Epidural analgesia</td>
<td>Total spinal</td>
<td>Death</td>
</tr>
<tr>
<td>30.</td>
<td>M, 54</td>
<td>MS</td>
<td>Back pain</td>
<td>Epidural analgesia</td>
<td>Total spinal</td>
<td>AMI, bedridden</td>
</tr>
<tr>
<td>31.</td>
<td>F, 86</td>
<td>No</td>
<td>Femur fracture</td>
<td>CSE</td>
<td>Paraplegia</td>
<td>Death after 7 months</td>
</tr>
<tr>
<td>32.</td>
<td>F, 28</td>
<td>Asthma</td>
<td>Varicose veins</td>
<td>Spinal</td>
<td>Paraparesis</td>
<td>Permanent</td>
</tr>
<tr>
<td>33.</td>
<td>F, 70</td>
<td>Rheumatoid arthritis</td>
<td>Total knee arthroplasty</td>
<td>Spinal</td>
<td>Paraparesis</td>
<td>Permanent</td>
</tr>
<tr>
<td>34.</td>
<td>M, 71</td>
<td>HA</td>
<td>Bilateral total knee arthroplasty</td>
<td>CSE</td>
<td>Epidural haematoma suspected</td>
<td>Recovery almost complete</td>
</tr>
<tr>
<td>35.</td>
<td>F, 55</td>
<td>No</td>
<td>Varicose veins</td>
<td>Spinal</td>
<td>Pain, sensory loss</td>
<td>&gt; 1 year</td>
</tr>
<tr>
<td>36.</td>
<td>F, 38</td>
<td>No</td>
<td>Hysterectomy</td>
<td>GA and epidural for pain relief</td>
<td>Pain: lower extremity</td>
<td>CRPS</td>
</tr>
<tr>
<td>37.</td>
<td>F, 55</td>
<td>No</td>
<td>Revision hip arthroplasty</td>
<td>CSA</td>
<td>Pain in lower extremity</td>
<td>&gt; 1 year</td>
</tr>
<tr>
<td>38.</td>
<td>F, 69</td>
<td>HA</td>
<td>Total knee arthroplasty</td>
<td>Spinal</td>
<td>Pain</td>
<td>CRPS</td>
</tr>
<tr>
<td>39.</td>
<td>F, 30</td>
<td>No</td>
<td>Labour pain</td>
<td>Spinal</td>
<td>Pain in lower extremity</td>
<td>&gt; 1 year</td>
</tr>
<tr>
<td>40.</td>
<td>F, 75</td>
<td>COPD, ASO</td>
<td>Vascular surgery</td>
<td>CSE</td>
<td>Pain</td>
<td>&gt; 1 year</td>
</tr>
<tr>
<td>41.</td>
<td>F, 43</td>
<td>No</td>
<td>Hysterectomy</td>
<td>GA and epidural catheter</td>
<td>MRI: Intradural blood</td>
<td>Pain</td>
</tr>
</tbody>
</table>

CSA, Continuous spinal anaesthesia; CSE, combined spinal and epidural; MRI, magnetic resonance imaging; CRPS, complex regional pain syndrome; GA, general anaesthesia; AMI, Acute myocardial infarction; HA, hypertension; DM, diabetes; MCC, coronary disease; CI, heart insufficiency; FA, atrial fibrillation; COPD, chronic obstructive pulmonary disease; ASO, arteriosclerosis; MS, multiple sclerosis.
The second patient did not experience any apparent consequences.

**Case 29.** Primigravida, 20 years old, 156 cm, 56 kg, had epidural analgesia for labour pain intended to be inserted at the L2-3 interspace. Ropivacaine 10 mg + fentanyl 25 μg were given, and within a few minutes, a second dose (8 mg + 20 μg, respectively) was injected. The effect of these doses was not documented on the chart. The anaesthetist left the room at 22:35 hours, and a nurse midwife was left to care for the patient. At 22:45 hours, the patient became unconscious and hypotensive. The patient was intubated and ventilated and an emergency caesarean section was initiated at 23:02 hours, but the patient died at 23:50 hours. The autopsy showed that the epidural catheter located at the Th12–L1 interspace with the catheter 8 cm intrathecally.

**Case 14.** Hypertensive female, 62 years old, 156 cm, 93 kg. Elective arthroscopy of the knee with spinal anaesthesia was planned. Wash with chlorhexidine solution with alcohol was performed before placing sterile drapes to her back. The anaesthetist wore sterile gloves, and a face mask. Spinal anaesthesia was made with a single puncture, using a G27 needle. The spinal anaesthetic, hyperbaric lidocaine 95 mg, was taken from a single dose ampoule. Two months later, the patient complained of headache and stiff neck, and a week later she developed visual disturbances. Magnetic resonance imaging (MRI) showed brain ischemia and infarction. She succumbed 9 days later. Autopsy revealed brain and spine abscesses.

**Case 3.** Male, 85 years old, 88 kg, history of cardiac disease and spinal stenosis, hip arthrosis. His general condition would not permit arthroplasty and, therefore, he was given a single dose epidural analgesia for his hip pain. The epidural was made at L1-2, and analgesia reached T10 after which it regressed. Later, however, sensory and motor block of the legs returned and progressed to paraparesis. One week later, computed tomography (CT) of the lumbar spine suggested air in the epidural space. Subsequently, MRI showed a prominent haematoma compressing the medulla at Th10-11. His general condition prohibited surgical intervention, and he became paraplegic. Three months later, he developed deep venous thrombosis, and 2 weeks thereafter, he died following an acute myocardial infarction.

**Case 31.** Female, 86 years old, 162 cm, 75 kg, otherwise healthy, was admitted for a fracture of the hip. Surgery was performed under combined spinal anaesthesia (16 mg bupivacaine) and a post-operative epidural infusion of levobupivacaine 1.25 mg/ml + fentanyl 5 μg/ml, 4 ml/h. On her second post-operative day, the epidural catheter was removed, but on the fourth day, sensory and motor block of the legs became evident. MRI did not show any compressive changes although an electroneuromyography examination (ENMG) revealed fresh damage. The patient became paraplegic, and a second MRI showed possible polyradiculitis. A second ENMG displayed total damage of the L4 nerve root and bilateral fresh damage at L1-S1. She died within 7 months of complications due to her paraplegia.

**Neuraxial haematoma**

The 13 neuraxial haematomata are shown in Table 1 (nine epidural, two subdural, and two subarachnoid). In 10 instances, active antithrombotic prophylaxis was administered, but in six cases the timing of the antithrombotic medication in relation to the neuraxial puncture was not in accordance with the 2010 recommendations. In two patients, fondaparinux (a factor Xa inhibitor) was given. Most patients had an epidural catheter through which they received low concentrations of levobupivacaine (1.25–2.5 mg/ml) or ropivacaine (2 mg/ml) with or without fentanyl.

Of the patients with haematoma, four became paraplegic and another developed cauda equina syndrome. Four other patients remained paraparetic, while another two of them needed a walking frame and were incontinent. Only one person remained without symptoms. One other patient remained paraplegic and died within 4 months (see above, case 3).
Eight patients underwent laminectomy and evacuation of their haematoma; but only one – operated 16 hours after the symptoms appeared – recovered.

Of the epidural haematoma, one was as a result of a single spinal puncture, three appeared during the epidural treatment, and five others took place after the epidural catheter was removed. One subdural and one subarachnoid haematoma occurred after spinal puncture during combined spinal and epidural (CSE) technique. In the case with subarachnoid haematoma, blood from the spinal needle was noticed during the attempted dural puncture.

Infections
Four patients disclosed epidural abscesses. Two of these individuals were treated conservatively, while two others had surgical intervention. Three patients completely recovered, and the fourth who complained of pain in the back was gradually recuperating.

Eight patients suffered meningitis (seven related to spinal and one to epidural puncture). One of these patients died (see above, case 14). The remaining patients recovered with antibiotic therapy. Although all cerebrospinal fluid (CSF) findings indicated bacterial infection (leucocytosis), bacteria (α-haemolytic streptococcus) was identified in only one case.

Other complications
Two patients manifested paraparesis (in one case drug toxicity was claimed, the other patient’s problem was probably aggravated by spinal canal stenosis). A third patient was left with cerebral damage related to a total spinal blockade.

One patient was initially suspected as having an epidural haematoma, but later the diagnosis was changed to severe spinal stenosis provoking persistent lumbar area pain.

In yet another patient with recent onset back pain and symptoms of neuraxial haematoma, the MRI revealed only traces of blood but without compression of the spinal cord or nerves.

Six patients suffered nerve injury, which lasted over 1 year; of these, two have developed complex regional pain syndrome. Two of these six patients were diagnosed with spinal canal stenosis.

Outcome
Of the 41 patients with serious complications, 13 completely recovered, and two were steadily improving with only minor disturbances. One patient remains bedridden, and four are paraplegic; six patients are paraparetic, one is with cauda syndrome, while two remain incontinent as well require a walking frame. Six persons suffer from single nerve injury (two with CRPS). Finally, six patients have died. Permanent complications were predominantly seen in elderly individuals and in those who underwent orthopaedic surgery. Most cases involved epidural catheterisation (either alone, together with general anaesthesia or with spinal (CSE) (Table 4).

Estimates of complication rates
Approximately 1.4 million central neuraxial blocks were carried out during the study period. Approxi-
mately one death occurred in 233,000 patients, while one serious complication in 35,000, and one permanent injury in 53,000 neuraxial blocks was found.

Fatalities occurred in 1 : 775,000 spinal anaesthesia, 1 : 62,000 epidurals related to surgery or acute pain relief, 1 : 12,000 epidurals for chronic pain relief, 1 : 89,000 combined spinal and epidural for surgery and 1 : 144,000 epidurals for labour. Respectively, permanent complications occurred in 1 : 59,600 spinal anaesthesia, 1 : 15,400 involving epidurals for surgery or acute pain relief, 1 : 2400 in epidurals for chronic pain relief, 1 : 9900 in the case of combined spinal and epidural for surgery, 1 : 144,000 epidurals for labour, and 1 : 66,000 spinal anaesthesia for labour. Neuraxial haematoma after spinal block occurred in 1 : 775,000 and after epidural block in 1 : 26,400, and combined spinal and epidural 1 : 17,800.

Discussion

General considerations and comparison to previous studies

The risk of developing a serious complication after central neuraxial block between 2000 and 2009 was 1 in 35,000. When comparing this to the earlier study here using a similar method of data collection, it seems that the number of complications has decreased (in that study the number of serious injuries were 1 : 22,000 following spinal and 1 : 19,200 following epidural).8 In any case, the types of complications do differ. A comprehensive prospective UK study4 found that central neuraxial block has a low incidence of complications, of which many resolve within 6 months. They presented ‘pessimistic’ (‘worst case scenarios’) and ‘optimistic’ (‘best case scenarios’) incidences; all cases where the cause was judged to be unlikely were excluded from the optimistic analysis. The optimistic incidence for permanent injury was 2.0 (confidence interval [CI] 1.1–3.3) per 100,000 cases and the pessimistic 4.2 (CI 2.9–6.1). The risk for permanent complication after central neuraxial block in our material was 1.9 : 100,000 which is within the ‘optimistic’ confidence interval of the UK study. On the other hand, our incidence is clearly smaller than that of Moen et al.3 who performed a retrospective study of serious neurologic complications after central neuraxial blocks during a 10-year period (1990–1999). The information obtained from their postal survey and administrative files revealed 127 serious situations, Permanent neurologic damage was observed in 85. In their thorough work, they estimated that the incidence of complications after spinal blockade was between 1 : 20,000 and 1 : 30,000 and following epidural blockade 1 : 25,000. Interestingly, only two of their 33 epidural haematomata were found in the Swedish Patient Insurance Claims. Of course, we cannot rule out that some of the major complications also in Finland have not been reported. On the other hand, at least in Finland, there has been a marked increase in the activity of reporting claims as compared to the study (1987–1993).8 During the period 2000–2009, the annual number of claims has been stable, at about 8000 claims. During the period 1987–1993 when the insurance system was relatively new, the annual number of claims rose from 2500 to 5700 (mean 3600).

Keeping in mind that this material may not be complete, one can assume that most major incidents in Finland during this study period are presented for the following reasons. All the public hospitals and all private practitioners must contribute to the PIC. It handles all the claims in a centralized fashion, makes the decisions and pays the compensation. If patients feel that there has been injury or improper treatment during their care, they can contact the ombudsman to help with the complaint and claim. Such an ombudsman has been available in every hospital since 1993. He helps the patient with the complaint and claim. In Finland, the PIC/ombudsman system is well known and easily accessible.

The denominator, number of anaesthesias during the period, is an estimate, but can be considered reasonably reliable. In Finland with 5.5 million inhabitants the practice from hospital to hospital is reasonably similar. Thus, even though few hospitals did not answer the questionnaire and some gave exact numbers, some only estimates, we can extrapolate the approximate number of neuraxial blocks during this period. This number has remained almost the same when compared with the older study.8 That study comprised 67 hospitals. Since then, several of the units have merged, and others no longer provide surgical services – thus in this survey, the number of hospitals has decreased.

Anaesthesia files often lacked important details about the technical aspects of the performed neuraxial procedures (number of attempts, puncture site, size of the needle, etc.). This information is hard to remember afterwards and, for medicolegal reasons, both for the patient and the anaesthetist, it would be crucial to document all the relevant information during the procedure.16 However, for the purpose of this study the relevant variables could be found in most cases.
Types of complications

Fatalities. Six patients died, two as a result of an error in the epidural infusion. Often, the electronic pumps used for continuous blocks are actually developed for intravenous infusion and can therefore deliver doses up to even 100 ml/h. This bears the risk of unintentional overdose as seen in our case 27 (roughly 10 times overdose). Many so-called disposable pumps yield a maximum rate of about 10 ml/h and thus might be safer in this context. Besides, it might be warranted to introduce dedicated pumps for neuraxial techniques. Similarly, there has been discussion in separating the Luer connector systems for intravenous from those for neuraxial use.17 Actually, to prevent wrong route errors, the UK National Patient Safety Agency has given a patient safety alert stating that by 1 April 2013, all regional anaesthesia infusions and bolus doses should be performed with devices with connectors that will be incompatible with intravenous equipment.* Obviously, medication errors are not restricted to neuraxial anaesthesia; e.g., a frequency of one mistake in 133 anaesthetics18 has been mentioned. Fortunately, most of them do not result in serious sequel. Reporting and thereby learning from such faults may reduce drug errors in the long run.18

Potassium chloride given epidurally has resulted in temporary or permanent motor blockade and in some instances even death after persisting paraplegia.19,20 Our patient was elderly, and his death was as a result of a myocardial infarction, which probably was a consequence of the potassium chloride intoxication. To minimize such errors, epidural infusions should be prepared centrally in pharmacy.

One death was the result of a total spinal block, which was not detected and treated early enough. The second dose was obviously given too fast after the first one. The total dose injected however was not excessive – ropivacaine 18 mg only along with fentanyl 45 μg. Unfortunately, the test dose to rule out an intrathecal injection is not always reliable.21 The reason for one death was infection but with 2-month delay between the anaesthesia and appearance of symptoms. However, the autopsy revealed cerebral and spinal abscesses and the lumbar puncture as route of entrance cannot be ruled out. This complication occurred although the generally recommended aseptic precautions were used.22

Bradycardia after spinal anaesthesia may lead to cardiac arrest and death if not promptly treated.23,24 In contrast to the previous analysis,8 we found no deaths associated with cardiac arrest following spinal anaesthesia. This is perhaps due to the fact that nowadays it is a common practice in Finland to always have atropine sulphate and a vasopressor such as ephedrine on hand in syringes when performing central blocks. This together with vigilance most probably helps to prevent serious consequences of sudden bradycardia and hypotension after spinal anaesthesia.

Haematoma. Thirteen neuraxial haematoma compressing the spinal cord/nerves were reported from the 1.4 million central neuraxial blocks made, i.e., an incidence of 1 : 110,000. This incidence is greater than that of the first Finnish study (5 : 720,000 patients, i.e., 1 : 143,000). Moen et al.3 had a much higher incidence of haematoma (total incidence after epidural 1 : 10,300 and 1 : 480,000 after spinal anaesthesia). In addition, they calculated that the risk of epidural haematoma was even 1 : 3600 in females undergoing knee arthroplasty. A recent analysis7 estimated the incidence of neuraxial haematoma to be 1 : 6600 in non-obstetric patients with epidural blocks (the authors described five thoracic epidural haematoma and, one intracranial haematoma after a lumbar epidural). This particular material was collected through a network in which 19 hospitals collect regional anaesthesia-related complications on a voluntary basis.

The use of epidural analgesia after orthopaedic operations has diminished partly because of an increased use of potent antithrombotic prophylaxis regimens and the introduction of other options for pain relief (for, example, peripheral blocks, local infiltration analgesia).25,26 There have been several guidelines from different anaesthesiology associations for the use of thromboprophylaxis after central neuraxial blocks.11–15 The newest versions have been published after the end of our study period. However, in Finland there were national recommendations dating from 199914 and 2004,15 and these did not markedly differ from the latest recommendations. In our material, in six out of 10 patients with active thromboprophylaxis and suffering a neuraxial haematoma, the timing of the antithrombotic medication in relation to the application of the neuraxial technique would not have been in accordance with the 2010 Scandinavian guidelines.11 The recommended doses were exceeded in three instances, and in three others, the time frame for the puncture

Complications associated with neuraxial anaesthesia

for the removal of the catheter was breached. Two patients given fondaparinux had their catheter removed during the first 20 hours after their last dose. The present recommendations suggest a minimum of 36 hours between the last fondaparinux dose and catheter removal. To our knowledge, these are the first reported cases of neuraxial haematoma in conjunction with fondaparinux and central neuraxial block.

However, even if treatment is made according to the present guidelines, it does not necessarily protect from neuraxial haematoma formation as observed in our material in four patients. Also, three patients manifested haematomata even without having received antithrombotic therapy. It is well known that neuraxial haematoma can occur spontaneously for various reasons.

In our material, the occurrence of neuraxial haematoma was rare after a single dose spinal and in obstetric material. Instead, it was seen most frequently in orthopaedic surgery. This is in accordance to the study by Moen, where haematoma was most common in females undergoing total knee arthroplasty. In three of our cases, patients had vascular surgery, and the dose of low molecular weight heparin exceeded those recommended in the present guidelines. Patients having vascular surgery usually have comorbidities and thus an increased anaesthesia risk. In these patients, neuraxial anaesthesia and analgesia techniques offer several benefits, such as less post-operative pain and ileus and faster mobilization. Therefore, the administration of central neuraxial block in patients with increased risk of a neuraxial haematoma because of the concomitant use of low molecular weight heparins might be justifiable. Regardless of our results, no cases of epidural haematoma was found in a meta-analysis on 14,105 cardiovascular patients having epidural analgesia/anaesthesia. When extrapolated, the maximum expected rate was 1 : 4700.

Surgical intervention. When a compressive neuraxial haematoma is diagnosed, laminectomy should be performed within 6 to 48 hours. In a large retrospective study, 66% of patients operated within 12 hours recovered, but when the operation was performed in 12–24 hours, only 36% recovered. In Vandermeulen et al’s review, the best results were observed after surgery within 8 hours but, if surgery was delayed more than 24 hours, only 2/11 had good neurologic recovery. In the present material, one neuraxial haematoma was evacuated within 16 hours and still the patient recovered. On the other hand, there were cases where surgery was performed without delay, but the recovery was poor. The calculation of the time gap between the start of symptoms and the operation is often difficult, since many of these patients have epidural infusion analgesia which could mask the initial symptoms of the haematoma.

Subdural haematoma was observed in two cases, and a subarachnoid event in another two patients. In one of these patients, blood from the spinal needle was observed during the attempted CSE technique at the L3-4 level. In one case, there was dural tap at the Th11-12 interspace. According to Bills et al., subdural bleeding after lumbar puncture is due to puncture of the radiculomedullary vessels. These are found along the nerve roots and may be punctured, especially if the needle is not in the midline. The prognosis of subdural or subarachnoid bleeding, according to our results, is poor. Kreppel et al. do not differentiate the outcome of haematomata depending on different anatomical localisations. On the other hand, in a review by Domenicucci et al. there were 69 cases of subarachnoidal haematomata and in the 50 where a long-term follow up was possible the neurological conditions were good in 64% of cases. However, in only 45% lumbar puncture for diagnostics or anaesthesia preceded this complication.

Spinal stenosis and other factors. The presence of spinal stenosis is a risk factor for neurologic complications after central neuraxial blocks. At least eight patients of the present study manifested this condition. Unfortunately, often spinal stenosis becomes evident only after the complication has happened. Spinal stenosis is more frequently observed in elderly patients, who, on the other hand, would benefit from the neuraxial techniques. There were cases of permanent nerve damage where the reason remained unknown. According to MRI findings the spinal cord was not compressed nor were there any feasible explanations forwarded.

Infection. Prolonged epidural catheterisation (>3 days) carries with it a risk for epidural abscess. This was confirmed here as all five cases with epidural abscess had epidural catheter dwelling times in excess of three days (up to 14 days). Additionally, one patient had repeated single epidurals for chronic pain. Strict and thoughtful hygienic procedures could prevent the infectious complications. Immediate laminectomy has been recommended for verified epidural abscess. However, only two
patients in our material underwent this operation, in addition to antibiotic treatment. The others had only antibiotic therapy, but all recovered without neurologic sequelae. It must be kept in mind that laminectomy may not be necessary in the absence of neurologic deficits.

Meningitis was treated successfully with antibiotics. While the CSF cytology was suggestive of bacterial infection in seven cases, the bacterial culture was positive in only a single case. Baer reported three mortalities after meningitis with negative bacterial cultures.

The outcome here of haematoma and infections showed similar tendencies to that of Christie and McCabe, whose meningitis patients and five of the six with abscesses recovered completely. In contrast, only one out of three patients displaying haematoma recovered. However, their material consisted of only epidural techniques.

Safety of neuraxial blocks
The incidence of serious outcomes involving central neuraxial blocks was small, and it is possible that many of them could have been prevented. Many of the serious complications affected multi-morbid patients who would therefore carry an increased risk for anaesthesia – irrespective of whether it be neuraxial or general. Besides, those individuals would greatly benefit from neuraxial techniques. Seemingly epidural analgesia might be avoided in elderly orthopaedic patients; on the other hand, it provides good pain relief and diminishes such morbidities as stroke, myocardial infarction, pulmonary complications, and infection. Compared to general anaesthesia, major complications occur less often after surgery and pain relief when performed under neuraxial or other regional anaesthesia and even the need of critical care services or 30-day mortality is diminished.

Conclusion
The closed claims from the Finnish Patient Insurance Center provided a database for analysing various types of complications. Here, we presented the claims related to central neuraxial blocks over the past decade. The number of serious complications is small (fatality 1: 233,000, serious complications 1: 35,000). Patients who carried the greatest risk were the elderly who frequently had comorbidities and thus had an increased overall anaesthesia risk. While the number of claims has markedly increased since the 1997 study, the incidence of serious complications remains, broadly speaking, unchanged. The risk of cardiac arrest during spinal anaesthesia has decreased, while that for lumbar neuraxial haematoma has grown. The use of potent antithrombotic agents in recent years has increased the probability of compressing haematoma. In many haematoma cases, the timing of administration of the thrombosis prophylaxis in relation to the neuraxial technique did not adhere to the present guidelines. Therefore, these guidelines should be emphasized.

Conflicts of interest: There is no relevant conflict of interest.

Funding: The study was supported by a grant from the Orton Research Institute, Invalid Foundation, Helsinki.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Questionnaire for the number of the procedures.