ORIGINAL ARTICLE

Incidence of spinal haematoma after epidural puncture: analysis from the German network for safety in regional anaesthesia

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Context The incidence of epidural haematoma after epidural anaesthesia is uncertain.

Objective To quantify epidural haematoma after epidural anaesthesia in 2008 and 2009 in a network for safety in regional anaesthesia in Germany.

Design Analysis of data systematically documented within the German network for safety in regional anaesthesia.

Setting A regional anaesthesia register for clinics recording their clinical practice was set up according to a consented protocol. After checking the registry for the presence of epidural haematoma, all participating centres were asked for the number of epidural haematoma and the number of neuraxial procedures performed during the 2 years. Patient-specific information regarding procedures and outcome were requested.

Main outcome measures The incidence of epidural haematoma in the network with comorbidities, coagulation status and time from first symptoms, also the performance of MRI and laminectomy.

Results During a period of 2 years, 33 142 non-obstetric epidural blocks were performed. Five thoracic epidural and one cranial haematoma occurred.

Discussion The incidence of spinal haematoma was 1 : 6 628 in this general surgical population. When local anaesthetics are continuously applied, progressive motor block should increase the level of suspicion. When accompanied by pain or paraesthesia, progression to diagnosis by MRI is mandatory.

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Introduction

Despite the benefits and widespread use of epidural anaesthesia, haematoma formation as a complication remains a major safety topic. Although the incidence is low, it is a devastating complication potentially leading to irreversible neurological deficit. Several attempts have been made to improve estimates of the incidence, its management and risk factors.[1–4]

Single centres report the incidences of epidural haematoma over prolonged observation periods.[1,2,4] A survey in Sweden[3] found 33 spinal haematoma in 10 years, but at that time there were no national guidelines for neuraxial blockade and thromboembolism prophylaxis. A survey in the UK[5] found 40 vertebral canal haematoma in a 6-year period followed by an audit lasting 1 year in which five cases were reported.[6]

The development of spinal canal haematoma may depend on several risk factors relating to patients, procedures and drugs.[7,8] The anticoagulated patient, particularly, has been the subject of different guidelines and recommendations, which are not based on randomised controlled trials, and there is still a need for better understanding of risk factors. In 2006, several centres in Germany agreed to cooperate and share clinical data for regional anaesthesia.[9] A standardised, itemised, computer database was implemented by the network centres, providing a registry with the opportunity to analyse large datasets. In addition to global analysis of the entire registry, there is the opportunity for the comparison of different centres as a benchmarking exercise. Specific outcomes such as infection rates, success and failure rates and neurological complications are available for use by network members (centres) as a tool for continuous quality improvement. Within this network, we analysed the incidence and management of epidural haematoma following epidural procedures.

Materials and methods

To assess the incidence of spinal haematoma as a complication of epidural anaesthesia, data from the German network for regional anaesthesia were analysed.[9] The structure of the network was described recently.[9] Data collection and analysis were conducted at the main centre of the registry (Saarland University Hospital, Germany) and approval was sought from the local regulatory

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authority (Ärztekammer Saarland number Ha50/11). Approval did not require written consent, as the data were anonymous. To evaluate the incidence and analyse the use and nature of anticoagulation, conformity to guidelines, comorbidities and management, we searched the registry for epidural haematoma and contacted all members of the regional anaesthesia network to ask if an epidural hematoma related to epidural catheterisation had occurred between 1 January 2008 and 31 December 2009. We then screened for factors related to patients, procedures and drugs. All participating centres were asked to audit epidural anaesthetic procedures in 2008 and 2009. The evaluation included age, sex, comorbidities (especially renal function), level of puncture, number of attempts or procedure-related complications such as bloody taps. Detailed data regarding diagnostic [e.g. international normalised ratio (INR), partial thromboplastin time (PTT) and anti-Xa activity] and therapeutic interventions (intervals between administration of anticoagulant and puncture, epidural puncture and subsequent anticoagulation, last administration of anticoagulant and removal of catheter, first symptoms, diagnostic imaging and surgical decompression) were supplied retrospectively by the corresponding centres. These data were not collected routinely in the network and so were specific to the index cases of spinal haematoma.

Results

Nineteen centres across Germany provided data. Ten were university and nine were tertiary hospitals. The number of beds ranged from 225 to 3213. All hospitals had resident staff. During the 2-year period, 34 265 non-obstetric epidural blocks were performed. Five thoracic epidural and one intracranial haematoma were detected.

Case 1

A 75-year-old man with a history of stenotic right coronary artery disease, a non-ST elevation myocardial infarction and aortic stenosis (0.8 cm^2) underwent colonic resection. Creatinine clearance was 34.9 $ml\,min^{-1}$ and standard coagulation tests were normal (INR 0.95, PTT 33 s, platelet count 339×10^9 $cells\,l^{-1}$). He took aspirin 100 mg daily. Thoracic epidural anaesthesia (TEA: T9/10) on the day of surgery was described as difficult with multiple attempts, but no bloody tap was reported. In the evening, 7 h after the end of surgery and 13 h after epidural puncture, he received enoxaparin (40 mg). On postoperative day 1, 13 h after the first dose of enoxaparin, the epidural catheter was pulled back 2 cm. Another dose of enoxaparin (20 mg) was given 1 h later. At 5 p.m. on that day, a motor block was reported but seemed to be reversible. During the next day (postoperative day 2), motor block reappeared at 1 p.m. together with reversible paraesthesia. One hour later, enoxaparin (40 mg) was given. Twelve hours after this last dose at 2 a.m. on postoperative day 3, he again complained of persistent paraesthesia. Computerised tomography (CT) 13 h later was inconclusive, but after another 2 h, an epidural hematoma was revealed by MRI. Emergency laminectomy was performed 2.5 h after diagnosis. Re-bleeding necessitated two surgical revisions. Neurological deficits gradually improved over several weeks.

Case 2

A 55-year-old woman (175 cm, 65 kg) underwent resection of a pleomorphic sarcoma of her right leg (cT2b cNO cMO G3). She had osteoporosis and had previous surgery for breast cancer, followed by multiple courses of chemotherapy and therapeutic hyperthermia. Her coagulation screen (INR 1, platelet count 268×10^9 $cells\,l^{-1}$, PTT 29 s) and renal function were normal (creatinine clearance 130 $ml\,min^{-1}$). No anticoagulation was given before surgery. During lumbar epidural catheter placement at L4/5 the dura was punctured. Perioperative blood loss was 2670 ml over 24 h. Volume replacement consisted of 2000-ml colloid, 3600-ml crystalloid and 2700-ml packed red blood cells which might have impaired coagulation. Postoperatively, the catheter provided successful analgesia. Two days later, she complained of fronto-nuchal headache that was resistant to treatment with analgesics, including opioids, metamizol and acetaminophen, and dizziness, tinnitus, nausea and vomiting followed. On the following day, the operation site was pain-free and the epidural catheter was removed. Later that day, she complained of weakness in her legs but no signs were evident. Nausea and vomiting persisted for another 3 days, and 4 days after catheter removal a blood patch was carried out. Three attempts were necessary to identify the epidural space at L3/4 and 15 ml of blood was injected. Another 5 days later, the fronto-nuchal headache reappeared. Apart from nausea and vomiting, there were no other neurological symptoms. Another 3 days later, MRI showed a subdural fronto-temporal haematoma with transtentorial herniation. This was immediately evacuated with full resolution of symptoms.

Case 3

A 73-year-old man (79 kg, 166 cm) with a pancreatic carcinoma underwent pancreaticoduodenectomy. He suffered from hypertension, allergic asthma and insulin-dependent diabetes. His coagulation profile was normal (INR 1.2, platelet count 182×10^9 $cells\,l^{-1}$, PTT 26 s) and moderate renal dysfunction was present (creatinine clearance 56 $ml\,min^{-1}$). In the evening before the operation (9 p.m.), he received certoparin (3000 U s.c.) for thromboprophylaxis. A thoracic epidural catheter was placed 11 h and 15 min later at T7/8. The skin was punctured twice and no blood was aspirated. Epidural analgesia continued with ropivacaine 0.2 %wt vol^{-1} at a rate of 5 $ml\,h^{-1}$. The next day, he complained of weakness

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and numbness in his left leg. These symptoms disappeared with a dose reduction of the epidural local anaesthetic. Weakness and numbness reappeared the next day, but were reversed after further dose reduction. Sixteen hours after the last dose of certoparin, on the third postoperative day, the epidural catheter was removed in the presence of complete motor block. As the motor block persisted, a CT scan was performed 10 h later and revealed an epidural haematoma at T6/7. Another 13 h later, MRI confirmed haematoma at Th4–7 with myelomalacia. Surgical evacuation was considered but discounted due to the low chance of improvement. Paraplegia at T6 level persisted.

Case 4

A 65-year-old woman (50 kg, 150 cm) with Barrett-type carcinoma of the oesophagus was scheduled for transhiatal extended gastrectomy. Her medical history included a right-sided hemicolectomy, chronic cholecystitis, arterial hypertension, frequent headaches and depression. There was no history of coagulopathy or impaired renal function and preoperative coagulation tests were normal (INR 1.18, platelet count 592×10^9 cells l^{-1}, PTT 29 s, creatinine clearance 89 ml min^{-1}). Two attempts were needed to place TEA at T10/11 without perceived perforation of the dura or aspiration of blood. Enoxaparin 20 mg had been administered 13 h before placement of the epidural catheter. Postoperative anticoagulation on the ICU was initiated with unfractionated heparin and adjusted to current PTT levels. On postoperative day 7, heparin was switched back to enoxaparin (20 mg). Seventeen hours after the last dose of enoxaparin, the epidural catheter was removed accidentally and 7 h later the next dose of enoxaparin was given. Another 11 h later, she was unable to stand and 5 h after that later she complained of pain in her legs and motor block became complete. MRI another 5 h later showed a suspicious subdural area extending from T7 to T8. The subsequent laminectomy 4.5 h later revealed a subdural haematoma ranging from T4 to T6 with signs of dural perforation. Neurological deficits gradually improved but did not resolve completely.

Characteristic data are summarised in Table 1. Due to a pending legal action in cases 5 and 6 we did not receive detailed information.

Discussion

The true incidence of epidural haematoma formation is difficult to determine despite several attempts to quantify its occurrence and improve our knowledge of risk factors and best management strategies.

Current published estimations of incidence are based on either nationwide surveys of differing quality or single-centre reports. Following the introduction of enoxaparin in the USA, Schroeder[10] found 17 epidural hematoma after epidural anaesthesia in the manufacturer's reports between 1993 and 1997. In this series, an estimate of

Table 1 Descriptive patient data, time course of diagnostic, therapeutic interventions and outcome

Case	Creatinine clearance (ml min^{-1})	Epidural puncture site	Attempts	Time of s.c. LMWH before cath insertion (hh:min)	Time of s.c. LMWH after cath insertion (hh:min)	Time of s.c. LMWH before cath removal (hh:min)	Time of s.c. LMWH after cath removal (hh:min)	Time 1[a] (h)	Time 2[b] (h)	Neurological outcome
1	35	T9/10	>2	n.a.	13:00	20:00	1:00[a]	15	2.5	Partial recovery
2	130	L4/5	1	n.a.	n.a.	n.a.	n.a.	–	–	Full recovery
3	57	T7/8	2	11:15	11:00	16:00	n.a.	10	–	Permanent deficit
4	89	T10/11	2	13:00	>12:00	17:00	07:00	10	4.5	partial recovery
5	82	T 7/8	1	n.a.	12:00	27:30	n.a.	3	0.7	permanent deficit
6	33.3	T9/10	1	34:00	04:30	n.a.	n.a.	4	0.5	permanent deficit

cath, catheter; LMWH, Low Molecular Weight Heparin; n.a., not applicable; s.c., subcutaneously. [a]Time 1, time from suspected symptom to MRI diagnosis. [b]Time 2, time from diagnosis to start of laminectomy if performed.

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112 000 patients were exposed to both enoxaparin and an epidural puncture, leading to a calculated incidence of one in 6 588. At that time, this figure was thought to be high, because guidelines with suggested intervals between administration of low molecular weight heparin (LMWH) and puncture, manipulation and removal of the catheter were not yet implemented. Moreover, the calculation was based on voluntary reporting of drug-related adverse events to the Food and Drug Administration (FDA), leaving the possibility of an under-reporting bias.

Moen *et al.*[3] used a postal survey combined with administrative data from the Swedish healthcare system to collect retrospective data from 1990 to 1999. Twenty-five epidural haematoma after epidural anaesthesia with a non-obstetric denominator estimated at 250 000 epidural blocks were found which corresponds to a rate of one in 10 000. Within the estimated subgroup of 18 000 women having epidural puncture for knee arthroplasty, they calculated a rate of one in 1 800 for spinal haematoma. The higher incidence of osteoporotic degenerative spinal anatomy in elderly women with a reduced epidural space and fragile vasculature together with an age-dependent reduction in renal function was subsequently identified as an important contributing factor.

The Royal College of Anaesthetists gathered data from National Health Service hospitals in the UK and found five cases between September 2006 and March 2008.[6] The respective denominator of 707 425 neuraxial blocks was calculated from a 2-week survey in the latter half of September 2006. Of these, 97 925 were perioperative non-obstetric epidurals resulting in a rate of one in 19 585, three times less frequent than in our present investigation. Reasons for this difference are unclear and Cook *et al.* discussed the uncertainty of identifying all relevant cases.

de Seze *et al.*[11] questioned centres for spinal cord injury in France and reported three spinal haematoma after epidural block. Postal surveys restricted to obstetric departments in the UK[12,13] reported only one haematoma in 614 000 parturient women.

Nationwide surveys may in principle have the advantage of large denominators. Single-centre experiences have also contributed to our current understanding; Popping *et al.*[4] reported three cases in 14 223 epidurals covering 9 years, Cameron *et al.*[1] reported two epidural haematoma in a series of 8 210 epidurals collected over 16 years and Christie and McCabe[2] reported three cases in a series of 8 100 epidurals over 6 years. Parvizi *et al.*[14] and Liu *et al.*[15] reviewed exclusively knee arthroplasty in patients treated with lumbar epidurals and anticoagulated with warfarin postoperatively without evidence of epidural haematoma. Jack and Scott[16] and Chakravarthy *et al.*[17] reported a series of patients treated with thoracic epidural analgesia for cardiac surgery over 10 and 13 years, respectively. Both reported zero incidence of epidural haematoma. Horlocker *et al.*[18] analysed complications following lumbar epidural catheterisation in anaesthetised patients and no epidural haematoma was reported. Osaka and Yamashita[19] found no haematoma formation in infants treated with epidural analgesia in 13 years. Katircioglu *et al.*,[20] Paech *et al.*,[21] Giebler *et al.*,[22] Albright and Forster[23] and Tanaka *et al.*[24] did not find any epidural haematoma in their single-centre reviews. Overall, many single centres do not report any epidural haematoma after epidural anaesthesia which is similar to our network for regional anaesthesia. To advance research on the incidence of epidural haematoma, large networks and nationwide database analyses are essential.

Apparently, the incidence of spinal haematoma formation after obstetric neuraxial analgesia is considerably lower than that in non-obstetric analgesia (Table 2).[1–4,6,11–27] Case reports of spinal haematoma after epidural analgesia are rare.[28] In fact, there is no report in conjunction with anticoagulation in the obstetric population. Together with the present data, the risk of spinal haematoma after non-obstetric perioperative epidural analgesia is one in 11 243 in contrast to one in 562 628 in the obstetric population.

The German network for regional anaesthesia was founded by the German Society of Anaesthesiology and Intensive Care (DGAI) with the German Professional Organisation of Anaesthesiologists (BDA) to improve systematically both documentation and analysis of regional anaesthesia procedures. Digital documentation systems are increasingly used because they allow continuous surveillance and quality management. Five epidural haematoma were reported by participating centres. During the 2 years, 33 142 epidural blocks excluding neuraxial blockade for obstetric anaesthesia were performed. Estimation of the incidence and risk for spinal haematoma is one in 6 628 in the general surgical population.

Among risk factors identified for spinal haematoma after neuraxial regional anaesthesia were lack of guidelines, administration of antithrombotic agents, female sex and difficult punctures. More than one attempt without a bloody tap was necessary in half of the present patients. Reviewing the literature between 1906 and 1994, Vandermeulen *et al.*[7] reported that the majority of 46 haematoma occurring after epidural block either had haemostatic abnormalities or difficult needle and catheter placements. Half of the epidural haematoma became apparent after catheter removal. In an analysis of 51 case reports, Wulf[8] confirmed that coagulopathies or anticoagulation dominate. An existing or acquired coagulopathy was present in a third of the 33 spinal haematoma reported in the Swedish study.[3] Also in closed claims analyses,[29] coagulopathies accounted for the majority of 36 cases reported between 1980 and 1999. Consequently, national and European societies

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Table 2 Vertebral canal haematoma formation after epidural analgesia

Source	Period (years)	Method	Non-obstetric TEA denominator	TEA+ cases	LEA denominator	LEA + cases	TEA/LEA denominator	Cases	Obstetric LEA denominator	Cases
Current	2	Reg, SCD	18 345	5	14 797	0	33 142	5	–	
[15]	6	3xSCD			4 365	0	4 365	0	–	
[6]	1,5	PS, Reg					97 925	5	161 500	0
[4]	9	SCD	10 198	0	3 385	3	13 583	3		
[20]	14	SCD					5 619		28 490	0
[11]	1	PS					67 725	3	362 232	0
[1]	16	SCD	5 954	1	2 256	1	8 210	2	–	
[2]	6	SCD					8 100	3	–	
[14]	8	SCD		–	11 235	0	11 235	0	–	
[16]	10	SCD	2 837	0		–	2 837	0	–	
[17]	13	SCD	2 113	0		–	2 113	0	–	
[3]	10	PS, AF, Reg					245 000	24	205 000	1
[19]	13	SCD	114	0	1 936	0	2 050	0	–	
[18]	7	SCD			4 298		4 298	0	–	
[23]	4	SCD					2 609	0	4 216	0
[21]	6	SCD		–		–			10 955	
[22]	12	SCD	4 184	0		–	4 184	0	–	
[25]	3	SCD					9 232	3		
[24]	16	SCD	7 548	0	9 891	0	17 439	0	–	
[26]	1	PS				–			13 007	0
[13]	2	PS				–			108 133	0
[27]	6	PS				–			288 351	1
[12]	5	PS				–			506 000	1
Total			51 293	6	52 163	4	539 666	48	1687 884	3
Incidence			1 in 8549		1 in 13 041		1 in 11 243		1 in 562 628	

Studies are identified by reference number. Obstetric and non-obstetric incidences are shown. Included are studies with denominators >1000. AF, administrative files; LEA+, cases with spinal canal haematoma; LEA, lumbar epidural analgesia; PS, postal survey; Reg, Registry; SCD, single-centre documentation; TEA, thoracic epidural analgesia; TEA/LEA, thoracic and lumbar combined; TEA+, cases with spinal canal haematoma. See text for further details.

have published guidelines to encourage safer intervals between anticoagulation, puncture and catheter removal.[30]

In the presence of severe renal impairment (creatinine clearance $<30\,ml\,min^{-1}$), enoxaparin has a longer elimination half-life and prophylactic doses should, therefore, be reduced. The moderately decreased renal function in our first case when 40 mg were given requires meticulous monitoring. One hour after catheter manipulation, another 20 mg of enoxaparin were given and may have contributed to an increased bleeding risk. There are no data available for certoparin prophylaxis in patients with renal impairment. Certoparin is contraindicated in patients with a creatinine clearance less than $30\,ml\,min^{-1}$. At present, in our third case, it remains speculative whether the moderate renal dysfunction contributed to the bleeding.

In our second case, a cranial subdural haematoma was diagnosed following epidural puncture and catheter placement. Cranial subdural haematoma formation is recognised as a rare but serious complication of spinal puncture. Currently in Germany, it is now accepted that this needs to be addressed during the process of informed consent for neuraxial procedures.[31]

In our first case, enoxaparin prophylaxis was started after surgery. This approach is as effective as the preoperative regime, but has the clear advantage that neuraxial puncture before surgery will not be affected, particularly in the presence of aspirin. Although both American and German guidelines for prophylaxis of venous thromboembolic disease[32,33] support the use of postoperative commencement of LMWH, the manufacturer of enoxaparin offers no such advice.

In our fourth case, the documented puncture site of the epidural space was three spaces below the most prominent impression of the haematoma in the MRI. Hemilaminectomy was performed at six segments more cranial suggesting the possibility of catheter induced perforation at T6. These discrepancies may be related to the known inaccuracy when intervertebral sites are determined[34] as well as the fact that catheter tips can travel several centimetres from the puncture site.

Case analysis and closed claims data suggest that patients first complain of progressive muscle weakness, followed by radicular back pain, sensory deficits and urinary retention before any other signs of spinal compression become apparent. In four of our five cases, muscle weakness was the first symptom. Weakness or numbness during epidural analgesia is more often attributed to local anaesthetic motor block than spinal cord compression. Lumbar epidural blocks produce more motor block than thoracic epidural analgesia and the necessary diagnostic steps for the former may then be delayed. For patients with new or unexpected neurological symptoms after epidural anaesthesia, MRI is the investigation of choice,[35–37] although CT myelography remains an option. The advantage of MRI is that haematoma, infection, abscess or a disc hernia can be discerned.[38]

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Vandermeulen *et al.*[39] and Horlocker and Wedel[40] suggested that the interval between the onset of paraplegia and surgery should be less than 8 h. Similarly, Bedforth *et al.*[41] suggested that no more than 4 h should elapse between the onset of new neurological signs and MRI scanning. Time from suspected pathological symptom to diagnostic imaging took from 3 to 15 h for the spinal epidural haematoma in our series. In two of the cases, CT instead of MRI scans were performed. Information is lacking as to why MRI was not performed within 4 h subsequent to neurological symptoms.

Even though conservative management of a spinal epidural haematoma has successfully been reported,[42] the most common procedure in the presence of neurological deficit is decompressive laminectomy.[43] Time from symptom to surgical evacuation in the present series took from 3.5 to 17.5 h. A national survey in the UK showed that in 2007, 10 of 32 cases in 2007 could not be managed within 24 h.[5]

Taken together, we conclude that the incidence of epidural haematoma after epidural analgesia may be higher than previous calculations suggest. Even if current recommendations for neuraxial punctures in the presence of anticoagulants are followed, epidural haematoma may occur. Because many epidural haematoma have been described in the absence of neuraxial punctures, we will not always be able to ascertain the cause. Whether renal function, age, female sex or type of surgery may be implicated clearly needs to be addressed in much larger data analyses. The clinical features consistently described include progressive motor block. Consequently, the continuous application of local anaesthetics should be immediately stopped in such cases. When accompanied by pain or paraesthesia, the level of suspicion should increase. Strict progression to diagnosis through MRI is warranted regardless of the time of day. Whenever neuraxial anaesthesia and analgesia is used, meticulous monitoring in a standardised manner with a high level of alertness is crucial. We strongly suggest that all patients with neuraxial catheters should be seen at least twice daily by qualified staff from a postoperative pain service as prescribed by the Operation and Procedure Code 'complex acute pain therapy'.[44] With the constant growth of information technology, the German network for regional anaesthesia offers a systematic basis to continuously improve our understanding and quality of patient care.

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