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Review Article

Learning from the law. A review of 21 years of litigation for nerve injury following central neuraxial blockade in obstetrics

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Summary

Medicolegal claims for neurological injury following the use of central neuraxial blockade in childbirth represent the second most common claim against obstetric anaesthetists. We present an analysis of 55 cases from a database of 368 obstetric anaesthetic claims. Common themes that emerge from the analysis include: consent; nature of nerve injury (non-anaesthetic; direct; chemical; compressive); recognition; and management. Specific advice arising from these cases includes: the importance of informing patients of the risks of nerve damage; keeping below the conus of the cord for intrathecal procedures; responding appropriately if a patient complains of paraesthesia; and having a high index of suspicion if recovery of normal neurological function is delayed. As ever, principles of good practice, including respect for patient autonomy, early provision of information, good communication and a high standard of record-keeping, will minimise the frustration of patients that can then lead them to seek a legal route to redress if they suffer an injury following central neuraxial blockade.

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Introduction

In this article, the second in our 'Learning from the Law' series [1], we draw again from the database of over 360 negligence claims relating to obstetric anaesthesia for which DB has acted as an expert witness to the courts between 1994 and 2015. This time we focus on nerve injury following central neuraxial blocks.

Over 700,000 central neuraxial blocks are carried out in UK hospitals each year, 45% of which are performed for obstetric indications [2]. Approximately 25% of women who labour in the UK will choose epidural analgesia (around 140,000 per year) and 92% of caesarean sections are carried out under central neuraxial blockade.

The Third National Audit Project (NAP3) of the Royal College of Anaesthetists confirmed that central neuraxial blockade in the obstetric population are 'very safe' and that, "*the risk balance of regional techniques in the obstetric population is so far tipped towards the benefit side of the equation, that no sensible commentator would argue against its continued use*" [2]. However, although complication rates are very low, when complications do occur they can be devastating. Even more so perhaps because the women affected are usually healthy before anaesthetic intervention and, not unreasonably, expect a positive birth experience free from long-term consequences.

As defined more fully in our previous article [1], medical negligence is a civil tort that occurs when a patient suffers harm due to the (in)actions of her doctor. To succeed, the claimant must prove that, on the balance of probability:

1 the doctor owed her a duty of care
2 the doctor's practice fell below an acceptable standard [3, 4]
3 she suffered harm as a direct consequence of the substandard care

Neurological injury is the second most common claim against obstetric anaesthetists after inadequate regional anaesthesia resulting in pain during caesarean delivery. However, despite relatively fewer claims for nerve injury, the associated cost is considerably greater, reflecting the spectrum of potential injury from mild, temporary paraesthesia, to devastating paraplegia [5].

These national figures were reflected in our database where 55 out of the 368 (15%) negligence claims involved a case of neurological injury following regional anaesthesia, compared with 76 (21%) claims for pain during caesarean section. Anaesthetic practice was assessed by DB to have been negligent in 141 out of 368 (38%) cases in the obstetric database overall, and in 25 out of the 55 cases involving nerve damage (46%).

As stated earlier, certain common themes emerged from this series of claims. These were consent; nerve injury (non-anaesthetic causes of nerve injury; direct trauma to the nerve; chemical injury; compressive injury); and recognition and management of complications.

Theme 1: consent

The consent process involves the two-way exchange of information. To fulfil the requirements of genuinely informed consent (i.e. not merely imparting information, but allowing time for reflection and discussion), this process should start in the antenatal setting and should not be confined to labour. There are obvious systemic and cultural barriers to this occurring routinely, but resources such as the Obstetric Anaesthetists' Association's information leaflets [6] are readily available to help in this process.

The quality of consent is not enhanced by gaining the patient's signature on a form and for this reason, written consent is not a legal requirement for obstetric central neuraxial blocks because it is given 'to facilitate another process (i.e. childbirth)' [7]. However, although the mother's signature is not required, she must be apprised of all material risks and the details of this conversation must be documented in the patient record. Regardless of the legal position, many hospitals insist on written consent, and anaesthetists should follow local protocols.

In our database, the information provided to patients relating to neuraxial anaesthesia was deemed to be inadequate and consequently negligent in 8 out of 55 cases (15%). While this figure represents the minority it is important to appreciate that this would be a far greater issue if today's legal standards were applied to historical claims. In more paternalistic times when 'doctor knew best', it was common practice not to warn of the risk of nerve damage, given its rarity. However, in today's post-*Montgomery* era, this is considered wholly unacceptable [8].

The UK Supreme Court ruled in *Montgomery* that patients must be warned of 'all material risks' and defined a material risk as any to which, 'that particular patient might attach significance', no matter how unlikely it is to materialise. Therefore, with regard to nerve injury, we should counsel the patient of the following: temporary nerve damage 1:1000 (rare); effects lasting > 6 months 1:13,000 (rare); and severe injury, including paralysis 1:250,000 (very rare) [9].

These data, derived from NAP3, are the best available given the difficulties we face when estimating risk involving very low probabilities. It can be equally difficult to set risk in a meaningful context for a specific patient [10], and this challenge may be even more apparent in the obstetric setting where, "*drugs, fatigue, pain or anxiety may compromise the capacity of the parturient*" [7]. In the eyes of the law [11] and of the Association of Anaesthetists, which echoes the legal position in its guidance [7], the influence of pain and drugs does not cause the mother to lose capacity except in the most exceptional of circumstances. Consequently, information should be shared and consent sought in the normal way.

Clinicians may be dubious on learning that women who labour are regarded legally as having capacity in all but the most extreme situations. To consider otherwise would be to enter a world of loss of autonomy for pregnant women in labour, a position that society would almost certainly not be prepared to tolerate.

Consent and birth plans

A birth plan is a statement of a woman's wishes and values. However, birth is an epistemically transformative process and so a woman may specify that she does not want epidural anaesthesia in her birth plan and go on to change her mind once labour starts. A woman with capacity (i.e. the vast majority, as described above) is not bound by her previous statement and has the absolute right to alter her views in the face of her new knowledge and experience, or even for no reason at all. In this situation, the epidural should be sited in the usual way.

If a capacitous woman refuses to give consent to any procedure during labour, this refusal must be respected. Should a woman genuinely lose capacity, the Association of Anaesthetists advises that the birth plan be viewed as an advance decision [12]. Therefore, if there is real conviction that the mother has lost her capacity, the anaesthetist should abide by her expressed wishes.

During the insertion of combined spinal-epidural anaesthesia for caesarean section, Mrs A was screaming in pain which she felt down her lower back and left leg with each of several attempts. She cried out for a general anaesthetic; the anaesthetist told her 'she would be grateful in the end.'

As well as changing her mind to request neuraxial anaesthesia, a woman is free to withdraw consent at any time during the process. Should the woman ask the anaesthetist to stop, they must obey, discuss her wishes with her and respect her subsequent decision, whether or not they agree with it. *"A mentally competent patient has the absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or no reason at all"* [13]. Under UK law, the fetus has no rights until the moment of birth and so any perceived fetal interests do not trump the wishes of the mother [11].

Theme 2: nerve injury

This theme can be further subdivided according to the mechanism of nerve damage; non-anaesthetic causes of nerve injury; direct nerve trauma; chemical injury (arachnoiditis); and compressive injury (epidural abscess or vertebral canal haematoma).

Non-anaesthetic causes of nerve injury

Mrs B was admitted for induction in her second pregnancy at 10 days past term. An epidural was inserted easily and uneventfully. The epidural, which was initially effective, needed topping up on three separate occasions due to pain in the right groin, before the delivery of a 4.5-kg baby in the occipito-posterior (OP) position.

Following delivery, Mrs B complained of numbness in her right leg and was found to have mild sensory and motor deficit in the distribution of the femoral nerve (L2, 3 and 4). The MRI was normal and nerve conduction studies confirmed a peripheral nerve lesion either of the femoral nerve or of the roots supplying it. The neurophysiologist concluded:

"This is probably a complication of the epidural with the anaesthetic being introduced into the subarachnoid space and pooling to produce both sacral and lumbar root damage."

Anaesthetists at the defendant hospital disagreed, citing birth trauma as the most likely cause; these views were dismissed until expert opinion was sought. DB agreed that the epidural was not responsible for the nerve damage. The Tuohy needle would have had to contact multiple nerve roots for it to have caused the demonstrated neuropathy. This is not anatomically feasible in the context of a single puncture and uncomplicated epidural insertion, during which no pain or paraesthesia was elicited.

The argument for drugs '*pooling*' in the subarachnoid space was spurious because there was no evidence of dural puncture; no evidence of spinal block; and a mixture of bupivacaine and fentanyl was used. These drugs are injected routinely into the subarachnoid space and do not cause nerve root damage. DB postulated that the damage was caused by compression of the nerve roots in the pelvis by the fetal head. This argument was supported by the following facts; the baby was large and in the OP position, thus enlarging further the head diameter entering the pelvis; the patient felt pain in the right groin during the second stage and this fits with compression of the upper right lumbar nerve roots; and the lesion fits very well the symptoms and signs of nerve root compression [14].

The claim against the anaesthetist was subsequently rejected.

Neurological lesions can result solely from the process of childbirth. Bromage estimated that pelvic neural compression occurs in 1 in 3000 deliveries, compression of nutrient arteries in 1 in 15,000 women and problems arising from arteriovenous malformations 1 in 20,000 times. These figures combined to make an incidence of postpartum neurological complications relating to obstetric causes of 1 in 2000 deliveries [15]. A prospective audit of all postpartum women found an incidence of 1 in 2530 for a neurological deficit lasting longer than 6 weeks, with epidural considered contributory in only 1 in 13,000 [16]. A recent prospective French study found an incidence of postpartum neuropathy of 0.3%, with 84% of lesions being in the femoral nerve territory and 69% resolving within six weeks [17]. This strongly suggests that childbirth by itself is a more common mechanism of nerve injury than neuraxial anaesthesia. In addition, positioning; instrumental delivery; ischaemic injury to the nerves as a result of hypotension or obstruction of the internal iliac arteries by the fetal head; or femoral compression resulting from oedema in late pregnancy may all result in postpartum neuropathies. Despite these recognised causes, if a woman has received neuraxial anaesthesia during childbirth, it seems that blame will often first be directed at the anaesthetist. By way of emphasis, we have a case in our series in which a woman suffering from postpartum paraesthesia attempted a claim against the anaesthetist although she had received neither epidural nor spinal anaesthesia! It is often only when an anaesthetic medicolegal opinion is sought that the obstetric nature of the injury is appreciated.

Direct nerve trauma

With respect to direct nerve trauma, negligence is assessed by considering two criteria. First, the level of insertion. When inserting a spinal needle, it is incumbent upon anaesthetists to take all reasonable precautions to ensure that the needle tip enters the subarachnoid space at a point below the termination of the spinal cord. Much has been written about this in the literature and this body of work will inform the opinion of any medical expert or judge assessing a case of neurological damage. Second, the actions following contact with a nerve. Should a correctly sited needle appear to contact the cord or filum terminale, a medical expert will examine the subsequent actions of the doctor to assess for negligence.

The spinal cord terminates at or above the L1/2 interspace in the majority, but extends down to the upper border of L2 in 43% of individuals and to its lower border in up to 20%. Thus, a needle inserted in a cranial direction at the L2/3 interspace would, theoretically, run the risk of hitting the cord in up to 20% of patients [18]. Tuffier's line (also known as the intercristal line) is commonly accepted as the landmark for the lower border of the body of L4 or the L4/5 interspace. However, studies show that Tuffier's line intersects the midline at or above L2/3 interspace in 33–51% of patients [19, 20]. This means that reliance on Tuffier's line can result in unintentionally high spinal placement in a significant number of patients.

To compound this problem, a paper published in 2000 demonstrated that anaesthetists were inaccurate in their identification of the lumbar spinal interspace at which a marker was positioned. Only 29% identified the space correctly. Of the remaining 71%, 68% thought the space was lower than it actually was; 51% were one space out in their estimate; 15.5% two spaces; 1% three spaces; and 0.5% were four spaces out [21]. This inaccuracy cannot be accounted for solely by the variability in Tuffier's line and it probably reflects a degree of overoptimistic assessment by anaesthetists, who tend to find higher spaces technically easier for insertion of spinal needles. The paper was accompanied by an editorial in which Professor F. Reynolds stated that "*the L2/3 interspace should not be an option*" [22]. This opinion has become accepted as conventional wisdom, and its implications for negligence claims are commented upon by DB in his subsequent editorial;

> *"The anaesthetist who is unfortunate enough to hit and damage a normally-terminating cord with a spinal needle is likely to find himself in a difficult position when it comes to a claim for medical negligence. With the professional literature replete with papers showing us the errors we tend to make when identifying spinal levels and warnings about the risk of placing a spinal needle too high, the Defence will be on the back foot from the outset"* [23].

An anaesthetist may believe the spinal needle entered at a particular level but if cord damage should result, an MRI scan is likely to reveal the true level of needle insertion; the courts will accept radiological evidence over the level documented. The use of ultrasound is not, at least at the time of writing, a standard of care for the insertion of neuraxial anaesthesia.

Of course, the dictat of needle insertion below L3 applies only to intrathecal (spinal) anaesthesia. It *is* acceptable to insert an obstetric epidural at any level in the lumbar, or even lower thoracic region, as we do not intend to breach the dura with the Tuohy needle.

Mrs C underwent elective caesarean for the delivery of her fifth child. Spinal insertion proved difficult and three attempts at L2/3 were documented, the last one causing pain and paraesthesia, described as "*immediate hot pain…like having a red-hot poker pushed down both legs*". Success was finally achieved at a level documented as L3/4. The anaesthetist commented that the patient may have an unusually low termination of the cord. Mrs C subsequently developed paraesthesia, weakness and urinary complications and an MRI performed several months later showed a syrinx centred around T12/L1.

The anaesthetist's estimation of level was judged to be incorrect and the damage was considered, on the balance of probability, to be caused by the spinal needle. Causation was attributed to this error, which represented substandard practice. The anaesthetist was found to be negligent and the case was settled by the Trust.

Close attention must be paid to the patient's response while inserting the spinal/Tuohy needle and when injecting the anaesthetic solution. Any complaint of tingling, lancinating shocks or pain distant to the site of insertion (especially in the legs) is highly suggestive of direct nerve contact. If any of these signs is elicited, the anaesthetist must stop. The needle should be partially or fully withdrawn, and inserted at a different angle or different interspace. It is not uncommon for the patient to experience fleeting, mild paraesthesia during the threading of an epidural catheter; this occurs frequently and is generally regarded as benign.

During spinal anaesthesia, injectate should be administered only after confirming that cerebrospinal fluid (CSF) flows freely from the needle hub as this suggests that the tip is lying free in the subarachnoid space and is not partially or fully embedded within nerve tissue. It is not sufficient simply to see fluid in the hub as this could have entered the needle during its passage through the CSF into the nerve; the fluid must flow freely. Many practitioners aspirate CSF from the spinal needle twice: once before beginning injection and for a second time half-way through to ensure that the tip remains free in the CSF.

The spinal procedure should be documented meticulously, including the number of attempts, any symptoms elicited, actions taken in light of these and the presence of free-flowing CSF. Significant negatives should also be recorded, for example, 'No paraesthesia, no complications'.

Should nerve injury follow delivery, the absence of paraesthesia or lancinating pain during insertion of the neuraxial block should reassure the anaesthetist, as it is highly unlikely for damage to be attributable to the needle/injectate in the absence of these signs. If appropriate consent has been sought and given, a safe level of insertion chosen and a recognised technique used, then contact with the nerve is not, in itself, negligent providing the correct remedial steps are taken following this complication.

Chemical injury – adhesive arachnoiditis

The link between neuraxial anaesthesia and arachnoiditis has long been recognised. In 1949, Mr Woolley and Mr Roe were both left paraplegic after undergoing spinal anaesthesia for routine surgery on the same day, in the same hospital, with the same anaesthetist. The Court found that phenol, used to sterilise the local anaesthetic ampoules, had penetrated the glass ampoules through microscopic cracks, but it is now believed that the needles and syringes were contaminated with descaling fluid, used to clean the sterilising baths over the preceding weekend [24]. The publicity surrounding the lawsuit led to a drastic decline in the use of spinal anaesthesia in the UK until its resurgence as a technique in the 1970s.

Rare though spinal/epidural related arachnoiditis may be, our database contains at least two such cases, and possibly as many as seven. One of these is the case of Mrs Angelique Sutcliffe [25], which received damning coverage in the media [26].

In 2001, Angelique Sutcliffe developed a progressive and debilitating adhesive arachnoiditis after an apparently uneventful spinal anaesthesia for elective caesarean section, for which only hyperbaric bupivacaine 0.5% was administered. The path of her deterioration was steep and inexorable. Within a few days she had severe back pain, with urinary retention following shortly afterwards. Two weeks after delivery, she had signs of raised intracranial pressure, necessitating the insertion of a ventriculoperitoneal shunt to treat obstructive hydrocephalus. She developed worsening and ascending sensory and motor neuropathy in her legs over the following weeks and having undergone further surgery to treat recurrent raised intracranial pressure, became progressively paraplegic with limited use of her arms. Her magnetic resonance imaging scans show a spinal cord severely damaged as a result of multiple dense adhesions [27].

At the time of acting as expert witness to this case, DB was unconvinced by the judge's findings that the equipment must, somehow, have become contaminated with chlorhexidine solution; there did not appear to be a plausible explanation as to how this happened. However, he

retracted this view following the devastating paralysis suffered in Australia by Grace Wang following the accidental injection of 8 ml of chlorhexidine 2% in alcohol via a Tuohy needle into her epidural space [27]. This mistake occurred when, following a bloody tap, the saline in the loss-of-resistance syringe was returned to the gallipot, staining the remaining saline pink. This blood–saline mixture was positioned next to the gallipot containing chlorhexidine, thereby aligning the holes in the 'Swiss Cheese' to catastrophic effect [28]. The error that befell Grace Wang demonstrated unequivocally the devastating effects of injecting chlorhexidine into the neuraxium and her deterioration mirrored exactly that of Angelique Sutcliffe.

The Association of Anaesthetists has produced a safety guideline for the use of chlorhexidine to achieve skin antisepsis, the salient points of which are in Table 1 [29]. NHS England also issued a Patient Safety Alert in 2015, warning against the practice of providing skin antisepsis agents and solutions intended for injection in 'open systems' (e.g. gallipots) in proximity to each other [30].

Summary of safety guideline: skin antisepsis for central neuraxial blockade [29]

Chlorhexidine in alcohol should be used for skin antisepsis.

Meticulous care in taking measures to prevent chlorhexidine from reaching the CSF:

1. Chlorhexidine should be kept well away from the drugs and equipment and should not be poured into containers on or near the same surface as the equipment for central neuraxial blocks. Equipment should be covered or protected while the antiseptic is applied by swab, applicator or spray.
2. The solution must be allowed to dry before the skin is palpated or punctured.
3. The operator should check his/her gloves for contamination with chlorhexidine. If there is any doubt, they should be changed before continuing the procedure.

Given the lack of convincing evidence of the antimicrobial superiority of a 2% solution of chlorhexidine in alcohol over a 0.5% solution, but the presence of clear evidence of the neurotoxicity of chlorhexidine, the use of a 0.5% solution should be preferred over a 2% solution for skin antisepsis before central neuraxial blocks.

Needless to say, practitioners and Trusts who choose to ignore this pragmatic advice will reap the legal consequences should harm befall their patients as a result.

Compressive injury

The risks of epidural abscess in the obstetric population are quoted as 1 in 50,000 [9]. We have no cases of suspected or confirmed epidural abscess in our database. Vertebral canal haematoma is a rare complication of neuraxial blockade. NAP3 estimated the risk in the obstetric population to be 1 in 170,000 [2]. We have one case of vertebral canal haematoma in our database. It left the patient paraplegic and serves as a stark reminder to remain ever vigilant for post-anaesthetic complications.

Ms D was pregnant with her first child. She underwent repair of a congenital cardiac abnormality as a child and, in later life, insertion of spinal rods to correct scoliosis. She was seen in the high-risk obstetric anaesthetic clinic where it was agreed that epidural should be attempted early in labour to maintain cardiovascular stability. She was fully informed of all material risks and the consent process was deemed satisfactory.

Insertion of the epidural was performed by a senior consultant anaesthetist who repeated the consent process before insertion. The epidural space was located easily and, apart from transient paraesthesia on threading of the catheter, which settled in the usual way, the procedure was easy and unremarkable. The epidural required several top ups during her protracted labour, and Ms D's baby was eventually delivered, by forceps extraction, in the early hours of the following morning, some 18 h after epidural insertion. The epidural required a further top up to facilitate this procedure. The epidural catheter was removed 2 h after delivery.

Ms D was reviewed on the morning anaesthetic ward round, nearly 5 h after the last dose of anaesthetic and 3 h after removal of the catheter. No assessment of motor function was made during this visit as the clinicians were focussed on her cardiovascular system. Later that morning, it was noted by a midwife that Ms D could not move her legs to allow examination but no further action was taken.

Ms D mentioned to a passing anaesthetist that her legs still felt heavy in the middle of the afternoon. She was given reassurance, but not formally assessed. In the late afternoon, 14 h after delivery, her vaginal pack was removed by an obstetrician who noted her immobile legs and requested a formal anaesthetic review. This took place 90 min later, over 24 h after catheter removal.

On assessment she was found to have full motor block and was referred to the neurosurgeons for urgent MRI. There was no out-of-hours MRI service at the hospital where she was an inpatient and so she was transferred to another facility. The MRI, performed 4 h after anaesthetic assessment, revealed a vertebral canal haematoma. She underwent emergency spinal decompression that night but her motor function did not recover and she remains paraplegic at the time of writing.

All aspects of the anaesthetic management before and during labour were deemed acceptable in the case of Ms D. However, the anaesthetists and midwives failed in their duty of care after delivery by failing to recognise and appreciate the implications of the lack of block regression. This leads us to our final theme.

Theme 3: recognition and management of complications

Follow-up of patients must be timely and include inquiry into the return of their motor and sensory function. Regardless of the total dose of epidural anaesthesia administered during labour and delivery, a block should be regressing by 4 h after the last dose. This '4-h rule' is referred to often in NAP3 [2] and will inform any expert assessing a claim. Failure of block regression by this time should alert the anaesthetist to the possibility of vertebral canal pathology. Urgent MRI (the gold standard for imaging suspected space-occupying lesions) and referral to the neurosurgeons must be considered.

Any patient who complains of pain or weakness following neuraxial anaesthesia should be assessed by an anaesthetist in a timely fashion. A full neurological examination should be conducted to identify the affected area and, if possible, to determine the cause of injury. If injury appears to result from direct nerve trauma (and does not represent an expanding lesion requiring emergency management), then in-patient referral to a neurologist for assessment is advisable. Electrophysiological studies can distinguish between central and peripheral nerve injury and can help in prognostication. They can be useful in assessing the longevity of nerve injury since new injuries take time to evolve. Therefore, electromyography performed within 72 h of suspected injury will reveal old neuropathies, but will not help in diagnosing new ones.

Conclusions

Although rare, nerve damage sustained in the course of neuraxial anaesthesia can be devastating. Financial awards against anaesthetists and their employers can therefore be concomitantly high. Although rare, the life-changing neurological complications associated with neuraxial blocks certainly constitute a 'material risk' and so each patient must be fully apprised of these and give their consent freely.

Neurological complications can occur by chance even in the most experienced and fastidious of hands, and nerve injury does not necessarily imply negligence on the part of the anaesthetist. However, given the propensity to blame the anaesthetic for any abnormal postpartum neurology it is prudent to be aware of this and to ensure that all entries into the medical records are sufficiently detailed and meticulous.

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