

A decorative graphic consisting of numerous thin, light blue lines radiating from a central point, creating a fan-like or sunburst effect. The lines are of varying lengths and angles, some pointing upwards and others downwards, creating a sense of movement and energy.

SECTION 1

PROJECT DESCRIPTION AND QUANTITATIVE ANALYSIS

NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists

CHAPTER 1: INTRODUCTION



Professor Tony Wildsmith

Spinal and epidural block techniques can produce highly effective pain relief for a wide variety of indications and may decrease patient morbidity after major surgery. Individual studies and metaanalyses have examined this effect and suggested benefit,¹⁻² with even cautious commentators accepting that there is merit in the suggestion.³ However, the case is not, for a variety of reasons, as well proven as might be assumed,⁴ and one aspect frequently omitted from the risk benefit analysis is possible complications of regional blocks.⁵ That serious complications can both occur and have a negative impact on the use of regional anaesthesia was seen after the Second World War. First, American neurologists published a series of cases of paraplegia following spinal anaesthesia,⁶ second, the report of the now infamous 'Woolley & Roe case'⁷ put this into United Kingdom (UK) context and led to the almost virtual abandonment of spinal and epidural techniques in the UK for more than two decades.

However, there was, from the early nineteen seventies, a progressive renaissance in use, started by a few determined enthusiasts who had kept the techniques in use in the UK and often driven by clinical developments in other specialties. This process started in obstetrics where regional techniques allow the mother greater involvement during both non-operative and operative delivery, and can contribute to better blood pressure control during

labour in the patient with pregnancy induced hypertension. The wider use of spinal and epidural block for operative delivery has almost certainly been the major factor in reducing the incidence of maternal death due solely to anaesthesia.⁸ In surgery, many new procedures (orthopaedic joint replacement, transurethral urology, vascular surgery) have been introduced to the benefit of an increasingly elderly population, but such patients suffer from much intercurrent disease and receive complex drug therapy, both of which complicate general anaesthesia. Regional techniques were (and still are) seen as providing clear benefits in these very diverse clinical situations, and it was felt generally that the risks of complications had been greatly exaggerated in the past. As noted already, there has been much clinical research aimed at identifying whether patient morbidity and mortality are improved by the use of regional anaesthetic techniques although it is doubtful if any of these studies were large enough to provide a definitive answer.

Metaanalysis is the usual way of dealing with problems when the size of individual studies precludes firm conclusions, and many took great encouragement from their interpretation of the most definitive of such reviews of the outcome of regional anaesthesia.² In fact, the actual conclusions published by Rodgers and colleagues in 2000 were far less definitive and more cautious than were interpreted by some.⁹ In addition, major concerns about a range of

Good practice in the management of continuous epidural analgesia in the hospital setting
RCoA 2004



complications, particularly of central nerve block (CNB) techniques, had also started to grow by then, although some problems seemed to relate to specific situations in other countries. For example, a high incidence of vertebral canal haematoma seen for a while in North America¹⁰ was apparently related to more frequent administration of enoxaparin for perioperative thromboprophylaxis than in Europe.¹¹ However, that did not mean that complications of regional anaesthesia were not occurring in the UK, there being sufficient concern and reports to prompt editorials and reviews.¹¹⁻¹⁵ The issue came fully to the fore in the UK with two individual cases which received considerable media attention,¹⁶⁻¹⁷ and a case series from Plymouth which, with a very high incidence of major sequelae, achieved some prominence.¹⁸ Evidence from Dundee suggesting that a significant proportion of blocks do not even function effectively¹⁹ also clouds the risk benefit assessment for the use of postoperative epidural analgesia.

Knowledge of the incidence of such complications should be an essential component of the clinical decision making and consent processes, but there are few good data which can be quoted to support such discussions leaving both patient and clinician in a quandary, first when it comes to deciding what is best for the patient, and then in obtaining informed consent. The latter

requires that patients are given information on both the risks and benefits of the proposed techniques, most specifically the incidence of complications in the UK setting. The figures which are sometimes quoted vary by a 100-fold (from 1:1,000 to 1:100,000) and this makes it impossible to obtain genuinely informed consent from patients offered these procedures. Major complications such as epidural abscess, meningitis and epidural haematoma are all rare so that most hospitals will see less than one of these per calendar year. Such events are often described in published case reports and have been used, by extrapolation, in attempts to assess their likely incidence,²⁰ but the validity of these extrapolations must be questioned because of incomplete case capture, publication bias and a lack of accurate denominator information. Many hospitals can report extended use of regional techniques without significant sequelae, but these data are virtually never published.

The best information available to date comes from two Scandinavian countries, Finland and Sweden, both with 'no fault' compensation schemes and populations small enough to allow for central reporting systems. In Finland the incidence of major complications was 1 in 22,000 after spinal anaesthesia and 1 in 19,000 after epidural block.²¹ In Sweden the figures were spinal: 1 in 20-30,000, obstetric epidural: 1 in 25,000, non-obstetric epidural: 1 in 3,600.²² These figures are markedly different to the single hospital UK report which recorded 12 major complications in 8,100 epidurals administered after major surgery (1 in 675),¹⁸ but this may represent anything from a high risk subset to an extreme example of case clustering. However, all of these reviews were retrospective, and bare figures for incidence ignore the final outcome. A major complication is always of concern, but the real anxiety relates to the incidence of permanent harm; the figure of 1 major complication for every 675 postoperative epidurals received much attention, but the fact that 75% of the patients made a full recovery

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did not.

This situation led Council of the Royal College of Anaesthetists to devote its third National Audit Project to this topic with a prospective attempt to identify both numerator (numbers of major complications) and denominator (number of central blocks – the census of activity) information for a 12-month period across the UK National Health Service (NHS). The aim would be to review patients with potentially life-changing complications across the breadth of anaesthetic and pain management practice with follow up (as far as an anonymous reporting system would allow) extending to six months so that final outcome, as well as incidence, could be assessed. No such project can guarantee complete collection of information, but widespread publicity and persistence ensured an eventual 100% return of good quality information during the census of activity stage of the project.²³ Collection of reports of complications was bound to be more difficult, but it was hoped that the use of multiple routes for their reporting would minimise omissions. In assessing what is reported in the following chapters, the success of the project must be judged against its primary aim: the identification of the incidence of permanent harm resulting from complications of spinal and epidural blocks, not the incidence of such complications, most of which can range from the trivial to the life threatening.

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CHAPTER 2: POTENTIAL BENEFITS OF CENTRAL NEURAXIAL BLOCK



Dr Tim Cook

INTRODUCTION

This project focuses entirely on major complications of central neuraxial block (CNB). This chapter aims to ensure the report does not present an unbalanced view of the overall usefulness of CNB and before addressing aspects of major harm caused by CNB, considers its potential benefits. Most controversy (and evidence) relates to perioperative techniques.

It is not a formal review of the subject but first indicates why there are inherent difficulties in deciding areas of benefit of CNB and second lists areas of proven or potential benefits of CNB. The chapter is not a fully 'balanced view' of the pros and cons of CNB, but merely illustrates areas of benefit.

1. DIFFICULTY IN INTERPRETATION OF THE EXISTING LITERATURE ON BENEFIT OF CNB

There are numerous randomised controlled trials (RCTs) examining whether CNB offers outcome benefits for patients, but their interpretation is difficult. The main area of controversy is whether CNB reduces major complications and improves survival after major surgery in high risk patients. Issues include the definition of what constitutes 'major' surgery, what makes a patient 'high risk', standardising and optimising CNB, which end-points should be examined and controlling for the multitude of other variables that may influence patient

outcome. Opinion also varies on whether analysis should be based on intention to treat (ITT) (i.e. including in a CNB group all patients in whom a block was attempted) or based on protocol adherence (i.e. including in the CNB group only those in whom CNB was successfully placed, effective and continued for the period prescribed in the protocol). Use of the different analyses will lead to considerably different results. Many studies are too small (under-powered) to detect clinically important differences.

The MASTER trial¹ is a useful example as it is quoted both as evidence for and against the benefit of CNB. The trial was designed to identify a clinically important difference in mortality in patients undergoing major abdominal surgery. The study was powered on the basis of an expected mortality of >10% and 888 patients were studied. Epidural technique (spinal level and drugs used) were not specified.² Depending on interpretation, 27–50% of patients randomised to epidural anaesthesia, either did not receive it at all, it was removed immediately after surgery, the catheter fell out or it did not provide adequate analgesia.^{3,4} Baseline mortality was 4.3%. Analysis was on intention to treat. The study reported no difference in mortality but a statistically significant reduction in respiratory failure in those randomised to the epidural group.

Wijeyesundera recently calculated that with this baseline mortality a study designed to detect a mortality difference would require around 55,000 participants³ and even one designed to detect a difference in a combined outcome of morbidity and mortality would require almost 6,000 patients.

This leads to two inferences, first the results of small trials with negative results may be due to type 2 errors. Second, that the use of RCTs to determine mortality differences may be impractical and, as Vasnath and Isaac pointed out, current evidence is based on under-powered RCTs.⁵

Alternatives to large RCTs are metaanalyses and systematic reviews but these suffer from problems such as inclusion of trials designed to study outcomes other than death, inclusion of old outmoded studies, bias from inclusion of small studies and the inclusion of heterogeneous studies.⁶ Correctly performed large RCTs provide better evidence than metaanalysis: up to a third of metaanalyses of small studies lead to opposite conclusions from subsequent large RCTs.^{7,8}

The MASTER group have robustly defended their study design and their results both in the overall population and in 'high risk' patients⁹ but whether the study supports or opposes epidural anaesthesia/analgesia remains inconclusive.

2. USE OF CNB IN UK PRACTICE

Perioperative

The current project has identified approximately 700,000 CNBs performed in the United Kingdom National Health Service per year.¹⁰ If we assume that half of obstetric CNB are placed, or continued for operative delivery then well over half a million CNB are performed for surgery in the UK. Somewhat surprisingly the number of anaesthetics, or operations performed in the UK is not known but estimates are of the order of 5–7 million.¹¹ A conservative estimate would therefore be that CNB is used for at least 8–10% of all operations in the UK.

Laparotomy

A recent national survey with a 65% return rate asked anaesthetists whether they would use an epidural for two hypothetical 75 year-old patients requiring abdominal surgery.¹² For an elective patient undergoing anterior resection more than 98% of respondents would use epidural anaesthesia/analgesia and for a less fit and acutely unwell patient with sepsis requiring emergency laparotomy 70% would. While much of reported practice did not follow best practice, it appears that epidural techniques remain popular in the UK for major abdominal surgery.

Obstetrics

The national obstetric anaesthetic database (NOAD)¹³ receives data from approximately three quarters of UK hospitals (data from the Obstetric Anaesthetists Association, 2008) and in 2005 CNB was used in almost 90% of over 500,000 Caesarean sections and for approximately 25% of 400,000 non-operative labours.

Orthopaedic surgery

The national joint registry (NJR)¹⁴ which collects data on surgical techniques used for lower limb joint replacement also collects anaesthetic data. This data has not been published and must be treated with extreme caution as it is not formally validated, but it records CNB as used for approximately 60% of primary and revision hip replacements and more than 50% of primary and revision knee replacements (unpublished data, National Joint Registry, 2008).

A recent national survey with 71% return rate reported over 75% of anaesthetists preferentially use CNB for anaesthetic management of surgery for fractured neck of femur, more than 95% of these CNBs being spinals.¹⁵

Trends in use of CNB

Despite this apparent widespread use of CNB several studies have reported a reduction (of up to 50%) in the use of perioperative epidural techniques in recent years. Christie reported

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marked reductions in the UK¹⁶ and the pattern is repeated, particularly since the MASTER study, in Australia,¹⁷ Canada³ and America.¹⁸

3. GENERAL POTENTIAL BENEFITS OF CNB

Improved pain relief

It is established beyond reasonable doubt that epidural analgesia can provide better analgesia than all other forms of postoperative analgesia.^{1,19–21}

Block's metaanalysis (100 studies)²⁰ reported that, compared to systemic opioids, all postoperative epidural analgesia techniques (irrespective of level of insertion or drug regimens) improved pain scores on each postoperative day, for all types of surgery and pain assessments (with the exception of thoracic epidural analgesia for rest pain). Minor side effects such as nausea and vomiting were also reduced.

Guay's metaanalysis (70 studies, 5,402 patients) found the addition of epidural anaesthesia/analgesia to general anaesthesia reduced pain scores at rest or during movement, and morphine use.²¹

A Cochrane review (9 studies, 711 patients) reported that after intra-abdominal surgery, epidural analgesia reduced pain scores throughout the first three postoperative days compared to patient controlled intravenous opioids.²²

Barington and Scott recently wrote in an editorial in the *Lancet* 'Provision of effective analgesia is our core business: it has substantial physiological and psychological benefits, and is regarded as a fundamental human right.' And 'The most durable and clearly defined benefit from epidural analgesia is improved analgesia... Pain after major surgery can be severe, and we think that in many cases pain relief alone is an unambiguous clinical indication for postoperative epidural analgesia.'²³

Effect on mortality following major surgery

Two moderately large RCTs found no overall difference in 30 day mortality in 'high risk' patients undergoing major surgery who were randomised to either general anaesthesia alone or with epidural anaesthesia and postoperative epidural analgesia.^{1,24}

The MASTER study¹ is described above. Park studied 1,021 patients having intra-abdominal surgery.²⁴ The epidural group received postoperative epidural morphine (without local anaesthetic) and the study design did not require thoracic placement of the epidural: both might be considered to fall short of best practice. The studies reported improved analgesia in the epidural group but methodological queries have been raised about both² and the likelihood of under-powering remains.

Wijeyesundera recently reported an 11% reduction in mortality rate when epidural techniques were used after major elective surgery.³ The study examined retrospective cohorts and had complex methodology: cases were selected from a database designed more for financial than clinical management and cohorts, which were clinically very dissimilar, were matched using propensity scoring. Surgery ranged from hip replacement to thoracotomy. Baseline mortality was <2% so the reduction in mortality led to a number needed to treat of 447 to save one life. While the benefit in this group is small, a similar relative risk reduction in a higher risk group, would be clinically important.²⁵

Rodgers, in a much reported and disputed metaanalysis (141 trials, 9,559 patients) reported a 30% reduction in mortality with CNB added to or used instead of general anaesthesia.²⁶

Wu reported postoperative epidural analgesia significantly reduced 30-day mortality by approximately 35% in almost 70,000 patients aged over 65.²⁷

Reduction in overall complications following major surgery

Yeager's very small study reporting that epidural analgesia markedly reduced complication rates (overall complications, cardiovascular failure, major infections, cortisol rise) in high risk patients was one of the earlier studies to suggest benefits outwith improved analgesia.²⁸

Rodgers metaanalysis²⁶ reported a reduction in deep vein thrombosis (DVT) by 44%, pulmonary embolism (PE) by 55%, transfusion requirements by 50%, pneumonia by 39%, and respiratory depression by 59%: all statistically significant effects. There were also non-significant reductions in myocardial infarction and renal failure.

Liu performed several reviews and metaanalyses. In a clinical review of epidural anaesthesia in the postoperative period he found a reduction in the surgical stress response, with theoretical secondary benefits in cardiovascular, respiratory, gastrointestinal and metabolic function.²⁹

Secondly he examined eighteen metaanalyses, ten systematic reviews, eight additional RCTs, and two observational database articles in an article described as a 'systematic update of the evidence'.³⁰ The narrative conclusions emphasised the importance of local anaesthetics in epidurals if outcome benefit is to be achieved and that most evidence of reduced cardiovascular and pulmonary complications is restricted to major vascular surgery and high-risk patients. Such evidence was reported as lacking for perineural techniques.

Finally the same authors reported that despite improving analgesia there is inadequate evidence that CNB improves other patient-reported outcomes (e.g. quality of life and quality of recovery).³¹ The authors reported significant methodological problems with included studies.

Guay's metaanalysis reported epidural anaesthesia/analgesia added to general anaesthesia reduced the incidence of

arrhythmia, time to tracheal extubation, intensive care unit stay and extent of stress response, while increasing vital capacity.²¹ Thoracic epidurals reduced the incidence of renal failure.

Reduced respiratory complications

The MASTER study showed a significant reduction in postoperative respiratory failure with a number needed to treat to prevent one episode of respiratory failure of 15.¹

Several metaanalyses confirm CNB reduces both infective and non-infective respiratory complications and respiratory failure.^{21,25,26,29,30,32}

Reduced cardiovascular complications

Guay reported perioperative epidural analgesia reduced arrhythmias.²¹

Beattie's metaanalysis (17 studies, 1,173 patients) reported that epidural analgesia, continued for a minimum of 24 hours, reduced postoperative myocardial infarction. A small decrease in the death rate was not statistically significant.³³

Others metaanalyses report reduced cardiovascular complications, including cardiovascular failure.²⁸⁻³⁰

Early return of normal gastrointestinal function

Several RCTs and metaanalyses report consistent evidence of earlier recovery of gastrointestinal function and no increase in anastomotic breakdown after major gastrointestinal surgery, with the effect most marked when epidural local anaesthetics are administered.^{29,34-40}

Interpretation is hampered by many inadequate studies, with use of lumbar epidurals for abdominal procedures, or the epidurals not containing sufficient local anaesthetic.³⁷

'Enhanced recovery' after major gastrointestinal surgery

Several Scandinavian studies report thoracic epidural anaesthesia (including local anaesthetic) as a central component of 'enhanced recovery' after gastro-intestinal

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surgery with reduced stress response, early resumption of gastrointestinal activity, no increase in anastomotic complications and markedly decreased length of stay.^{34–37,39,41–43} Other components of the enhanced recovery protocol include enforced early nutrition and mobilisation, balanced analgesia and avoidance of surgical tubes (e.g. drains and catheters).

Reduction in stress response

Metaanalysis and review reports that CNB consistently reduces hormonal stress response to surgery.^{21,29,42} Guay reported perioperative epidural reduced rises in blood levels of noradrenaline, adrenaline, cortisol and glucose.²¹

A recent RCT demonstrated that even low thoracic epidural anaesthesia significantly attenuates stress hormone rises (adrenaline, cortisol and gamma interferon: interleukin-10 ratio) and cellular immuno-suppression (lymphocyte and T-helper cell numbers).⁴⁴

Reduced surgical blood loss

A further metaanalysis by Guay (24 studies) showed CNB has a consistently beneficial effect on surgical blood loss.⁴⁵ Transfusion requirement was reduced after total hip replacement and spinal fusion while blood loss was reduced in retropubic prostatectomy, Caesarean section, bowel surgery, lumbar disc surgery and operations for fractured hip or peripheral vascular disease. This has been confirmed in metaanalyses of individual operations (see below).

Improved prevention of thromboembolic complications

A Cochrane review (259 patients) reported a 36% relative reduction and 17% absolute reduction in DVT with CNB (instead of general anaesthesia) for fractured hip surgery⁴⁶ and metaanalysis showed CNB reduced DVT and PE after hip replacement.⁴⁷

A systematic review concluded CNB reduced risk of DVT by half compared to general anaesthesia and also reduced bleeding.⁴⁸ The National



There is evidence CNB reduces thromboembolic complications, such as DVT (Photo provided courtesy of the University of California San Diego image collection).

Institute for Clinical Excellence's April 2007 report 'Venous thromboembolism; reducing the risk of venous thromboembolism' advocates regional anaesthesia to reduce thromboembolic disease.⁴⁹

Better tissue oxygenation and perfusion

Several studies have reported improved wound and generalised tissue oxygen tensions after major surgery, with potential benefit of increased wound healing and reduced infection rates.^{50,51} Animal work demonstrates improved gastrointestinal blood flow when thoracic epidural anaesthesia is used for gastrointestinal surgery.^{52,53}

4. BENEFIT OF CNB FOR SPECIFIC OPERATIONS**Knee replacement.**

Fowler's metaanalysis (8 non-blinded trials, 510 patients) reported epidurals to be as effective as peripheral nerve blocks, but leading to more frequent hypotension.⁵⁴

Fischer's systematic review with consensus recommendations, advocated spinal anaesthesia with femoral nerve block or spinal local anaesthesia and morphine as two of three evidence supported techniques for pain management.⁵⁵

Hip replacement

Mauermann's metaanalysis (10 studies, 330 patients) concluded CNB was associated with 4-fold less DVT and PE as well as less blood loss during surgery and markedly less need for transfusion.⁴⁷

Hip and knee replacement

A Cochrane review comparing epidural anaesthesia/analgesia with 'long-acting spinal anaesthesia' and systemic analgesia concluded that an epidural provided superior analgesia in the first six hours but not beyond (mostly after knee replacement).⁵⁶ Epidurals led to better control of pain during movement and were associated with less sedation, but more other minor side effects.

Fractured neck of femur.

A Cochrane (22 trials, 2,567 patients) reported CNB, rather than general anaesthesia, led to a 30% fall in early mortality (based on 8 trials, 1,668 patients) but no evidence of difference in longer term mortality at three months (6 trials, 726 patients) and one year (2 trials).⁵⁷ There was a significant reduction in DVTs and acute postoperative confusion.

A Canadian review concluded spinal anaesthesia for elderly patients with hip fracture was supported by level 1 and 2 evidence.⁵⁸

Vascular surgery

Subgroup analysis of Park's RCT of 1,021 patients reported epidurals led to a 40% reduction in major complications (myocardial infarction, stroke, and respiratory failure) in patients having abdominal aortic operations.²⁴ Time to extubation and time spent in intensive care were also markedly shorter.

Colorectal surgery

Gendall reported epidurals improved pain relief, reduced duration of ileus and had no effect on anastomotic leakage rates.⁴⁰ The authors concluded that limited evidence supports use of epidural analgesia (as part of a multimodal

regime) after laparoscopic surgery. Beneficial effects on pulmonary and cardiovascular systems and on thromboembolism were likely or possible, but unproven. Epidural analgesia alone did not reduce length of stay but has potential for cost savings due to reduced indirect costs. 'Enhanced recovery', with consensus recommendations for anaesthetists, was recently reviewed.⁵⁹

Thoracoabdominal surgery

Seller's recent systematic review and metaanalysis (30 trials, 4,294 patients) reported epidural analgesia added to general anaesthesia improved pain relief and reduced respiratory failure but had no effect on mortality.⁶⁰

Thoracotomy

Joshi's recent systematic review reported thoracic epidural analgesia provides better analgesia than intrathecal, intercostal and interpleural techniques as well as systemic analgesia.⁶¹ However paravertebral techniques were as effective and reduced pulmonary complications, which epidural analgesia did not. Either paravertebral or thoracic epidural techniques were recommended. A second systematic review and metaanalysis had very similar conclusions.⁶²

Coronary artery bypass graft

A metaanalysis by Liu reported thoracic epidural anaesthesia, compared to systemic opioids (15 trials, 1,178 patients), had no effect on mortality or myocardial infarction but reduced pain at rest and on movement, arrhythmia, pulmonary complications and time to extubation.⁶³ Intrathecal techniques (16 trials, 668 patients) had no effect on mortality, myocardial infarction, arrhythmia, time to extubation and only modestly improved pain control.

Hernia surgery in ex-premature infants

A Cochrane review examined three small trials (total 108 patients) and reported spinal anaesthesia, compared to general anaesthesia,

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showed no reduction in postoperative apnoea/bradypnoea unless pre-operative sedation was omitted.⁶⁴ Spinal anaesthesia was associated with a statistically non-significant reduction in the need for postoperative ventilation and an increase in technique failure.

Caesarean section

A Cochrane review (16 studies, 1,586 women) reported lesser reduction in haemocrit, a lower estimated maternal blood loss and less maternal nausea with CNB rather than general anaesthesia but no impact on early neonate condition.⁶⁵ Despite these apparently beneficial effects more women would favour general anaesthesia than CNB for subsequent procedures.

A Cochrane review (10 trials, 751 women) comparing spinal and epidural anaesthesia found them to be equivalent for failure rate, need for additional intraoperative analgesia, rates of conversion to general anaesthesia, maternal satisfaction, need for postoperative pain relief and neonatal intervention while spinal anaesthesia reduced anaesthetic time but increased the need for treatment of hypotension.⁶⁶

Combined spinal epidural (CSE) for labour analgesia.

A Cochrane review (19 trials, 2,658 women) examining 26 outcomes, found CSE required less rescue analgesia than low-dose epidural analgesia and was associated with less urinary retention but more itch.⁶⁷

Epidural analgesia in labour

A Cochrane review (21 studies, 6,664 women) of epidural analgesia compared to opioids or no analgesia was able to include only one study of pain assessment: showing efficacy of epidural analgesia.⁶⁸ Epidural analgesia increased instrumental, but not operative delivery. There was no effect on neonate condition or long-term maternal backache.

Cancer pain

A Cochrane review of delivery of opioids directly to the central nervous system for management of cancer pain (72 uncontrolled trials, 2,402 patients) reported excellent pain relief in 72% of patients with epidural, 62% with spinal and 73% with intracerebroventricular opioids.⁶⁹ CNB was more frequently associated with minor side effects but less frequency associated with respiratory depression, sedation and confusion than delivery directly to the brain.

5. THE PROSPECT WORKING GROUP

The PROSPECT Working Group conducts systematic reviews of postoperative pain management for specific surgical procedures (<http://www.postoppain.org>) and states it provides 'evidence-based consensus recommendations'. Recommendations are graded A–D, in accordance with the Oxford Centre for Evidence-Based Medicine.⁷⁰ These can be summarised as grade A (direct evidence from RCTs), grade B (transferable evidence from RCTs), grade C (retrospective studies or case series) and grade D (based on clinical practice).

Among recommendations for specific operations are

- ◆ **Thoracotomy:** numerous grade A recommendations for epidural techniques with local anaesthesia and opioids, including per- and postoperatively for 2–3 days. Also that thoracic epidural is preferable to lumbar techniques.
- ◆ **Total hip replacement:** single shot spinal local anaesthesia and opioid (grade A). Epidural analgesia continued after surgery, only in patients at high cardiopulmonary risk.
- ◆ **Total knee replacement:** spinal local anaesthesia and morphine (grade D).
- ◆ **Total abdominal hysterectomy:** single-dose spinal local anaesthetic plus strong opioid for both anaesthesia (grade D) and postoperative analgesia (grade A). Single dose spinal anaesthesia with or without light general anaesthesia in low-risk

patients (grade D) and epidural anaesthesia combined with light general anaesthesia or CSE in high-risk patients (grade A). Postoperative epidural analgesia in high-risk patients (grade A).

- ◆ *Open colonic surgery*: per-operative epidural anaesthesia and analgesia, with or without general anaesthesia, for routine use in patients without contra-indications (grade A). Epidural local anaesthetic and strong opioid in preference to either agent alone (grade A). General anaesthesia alone or CSE for routine anaesthesia are specifically not recommended (Grade D). Postoperative thoracic epidural local anaesthetic plus strong opioid for high-intensity pain, for routine use (grade A).

6. SUMMARY

There is good evidence, amounting to proof, that epidural analgesia can provide the most effective pain relief possible after major surgery. There is also evidence from numerous RCTs and metaanalyses that CNB in many circumstances has potential and actual outcome benefits. Evidence from both RCTs and metaanalyses has weaknesses.

In perioperative practice, the bulk of the evidence suggests that CNB has multiple actual and potential benefits. Evidence hints at major benefits such as reduced overall risk and perhaps mortality but the strongest evidence for this is restricted to high risk patients undergoing major surgery. The evidence is sufficiently unproven for both supporters and opponents to continue to argue that CNB is of benefit or is not, and there is little doubt these arguments will continue. The currently available evidence is hampered by small, poorly performed studies which do not use best practice in CNB. The evidence strongly indicates that for most benefit epidural anaesthesia/analgesia must be segmentally placed and must include a local anaesthetic drug. The actual and potential benefits must be balanced against evidence of an increase in some minor side effects and lack

of clear evidence of patient-reported benefit. Of course there are also rare major side effects of CNB (and similarly of alternatives to CNB).

The major complications of CNB are the subject of the rest of this report.

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CHAPTER 2
POTENTIAL BENEFITS OF CNB

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CHAPTER 3: PROJECT METHODS



Dr Tim Cook

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PROJECT AIMS AND OVERVIEW

The primary aim of the project was to determine the incidence of permanent injury attributable to central neuraxial blocks (CNB). The secondary aim was to follow the cohort of major complications reported to observe their progress over a minimum of six months.

A 2-part project was devised: first, an assessment of the number of CNBs performed annually in the UK National Health Service (NHS) (for denominator information); and second, an audit of the major complications of these procedures performed during a twelve month period (for numerator information). Discussions with the Centre of Research Ethics Committees (now National Research Ethics Service) indicated that ethical approval was not required, and the processes involved were agreed with the Patient Information Advisory Group of the Department of Health. The project was advertised widely throughout 2006 and 2007 through direct contact with the relevant organisations in anaesthesia, pain management, neurology, spinal surgery, radiology and neuroradiology (see acknowledgements section of the report). The aims and processes of the project were explained and the information was cascaded

down to the members of those organisations at regular intervals.

DENOMINATOR DATA

A detailed description of the first part, the 'census' survey (snapshot) to determine denominator information, has been published already¹ but a brief summary is appropriate here. Between March and September, 2006 the anaesthetic department of each NHS hospital believed to be performing surgery was contacted, asked to participate, and to nominate a 'local reporter' (LR) to co-ordinate the project locally. Each LR was asked to collect information on the number of CNBs performed over a two-week period at the end of September 2006 or an equivalent period at about that time. The blocks were classified as epidurals, spinals, combined spinal epidurals (CSEs) and caudals for each of the five indications: adult perioperative, obstetric (both labour analgesia and operative delivery) chronic pain, paediatric perioperative and administered by a non-anaesthetist. We did not request data on CNB that were attempted and failed as we considered it unlikely that all cases would be recorded reliably. No attempt was

made to record the level of epidural injection or any other details of insertion technique. For each category the reporters indicated whether their data were 'accurate', a 'close estimate' or an 'approximate estimate'. The mechanism of data collection was not specified and reminders to return information were sent at regular intervals by post, e-mail and telephone as necessary. Data were summed to give cumulative totals for a nominal two week period and, based on the annual results of one large district general hospital (Royal United Hospital, Bath), these figures were then multiplied by 25 to give an approximation of annual activity.

EVENT REPORTING (NUMERATOR DATA)

The same LR system was used to identify complications of CNB, but direct reports from any clinician in all relevant specialties were promoted with the aim of ensuring complete capture of all possible cases. We accepted reports even if the attempted CNB was abandoned: as such there is a potential to slightly overestimate the incidence of complications because we did not include these attempts in the denominator. The formal audit period was 1 September 2006 to 31 August 2007 inclusive, but reporting was actively encouraged until 31 March 2008 for the same reason. Information was sought on all major complications of CNB with the potential for serious patient harm including infection, haematoma, nerve damage, and cardiovascular collapse (Table 1). In addition, because of current concern about wrong route errors (i.e. a drug intended for the epidural or subarachnoid space inadvertently administered intravenously, or vice versa) [2] reports on these events were encouraged even when no injury occurred.

Primary notification of an event was by email, with reports accepted from any source. The project team was able to exclude obviously irrelevant cases at this stage, but otherwise the LR for the relevant hospital was asked to obtain the details and upload them to a secure,

Table 1. Complications sought in the audit process

Complication	Example
Spinal infections	vertebral canal abscess, meningitis
Spinal bleeding	vertebral canal haematoma
Major nerve damage	spinal cord damage, spinal cord infarction, paraplegia, major neuropathy
Wrong route injection errors	epidural/intrathecal drugs given intravenously or vice versa
Death where the anaesthetic/analgesic procedure is implicated as causal.	cardiovascular collapse, other

password-protected website (the National Confidential Acute Pain Critical Incident Audit, NCAPCIA, www.ncapcia.org.uk). The information requested depended on the type of incident, but the questions were designed to gain a full picture of the procedure and the presentation, severity and consequences of the complication. The NCAPCIA administrator (Dr David Counsell) was able to access these reports and request updates as required, being the only person who knew their source: this was essential to allow requests for clarification and updates of information while maintaining confidentiality. Each case was reviewed in detail by a panel representing all the specialties involved in the project (see Supporting organisations, review panel and acknowledgements), and the following details were confirmed:

- ◆ Type of block and indication for its performance (as described above). Procedures performed for the control of non-operative acute pain (e.g. fractured ribs, pancreatitis) were included in the perioperative group.
- ◆ Category of complication (Table 1);
- ◆ Correctness of diagnosis;
- ◆ Date of CNB within the audit period;

- ◆ CNB performed in an NHS hospital;
- ◆ Severity of patient outcome (see below), initially and at 6 months (or later where such information was available); and
- ◆ Causation: whether the CNB was the cause of the patient injury: certain, likely, possible, unlikely, no link.

Severity of complications

Severity of initial and final harm was recorded in a variety of ways. First, it was categorised according to the National Patient Safety Agency (NPSA) severity of outcome scale for patient safety incidents (table 2).³ Patient harm was graded as 'temporary' if the incident met the NPSA criteria for moderate injury, and 'permanent' if the outcome was worse than this (severe injury or death). Second, where injury was permanent, or assumed to be so, the features were classified as follows:

- ◆ Sensory only;
- ◆ Motor: motor weakness of whatever severity, with or without sensory symptoms;
- ◆ Paraplegia: paraplegia or tetraplegia with or without additional motor or sensory symptoms; and
- ◆ Death: classified as 'direct' (e.g. a cervical abscess leading to tetraplegia, respiratory failure and death) or 'indirect' when the CNB was followed by a series of other events leading to death (e.g. an abscess requiring decompression with good neurological recovery, but complicated by a fatal pulmonary embolism).

Interpretation of Reports

In a proportion of cases LRs were not able to provide full details of cases and patient progress, and some information was incomplete in spite of follow-up requests. Therefore the reports required some 'interpretation' by the review panel, which assumed the worst unless there was evidence to refute it:

- ◆ Diagnosis: where this was uncertain, cases were included: only those with clear evidence of incorrect diagnosis were excluded.

Table 2. National Patient Safety Agency severity of outcome scale for patient safety incidents

Grade of severity	Description
None	No harm (whether lack of harm was due to prevention or not)
Low	Minimal harm necessitating extra observation or minor treatment*
Moderate	Significant, but not permanent harm, or moderate increase in treatment**
Severe	Permanent harm due to the incident***
Death	Death due to the incident

* first aid, additional therapy or additional medication. Excludes extra stay in hospital, return to surgery or readmission.

** return to surgery, unplanned re-admission, prolonged episode of care as in or out patient or transfer to another area such as intensive care.

*** permanent lessening of bodily functions, sensory, motor, physiologic or intellectual.

- ◆ Causation and outcome: these were particularly difficult to judge in a number of cases, and this led to a decision to quote rates of complications in two ways, that is in terms of both 'worst' and 'best' case scenarios, defined in the results as 'pessimistic' and 'optimistic' incidences. When causation was judged certain, likely, possible or unlikely cases were included in the 'pessimistic' analysis, but those judged as unlikely were excluded from the 'optimistic' analysis. Similarly, efforts were made to determine patient outcome at 6 months after the CNB. Where outcome at 6 months (or later) was available this was used in the final judgement, but if such outcome information was only available from an earlier date that outcome was assumed to have persisted - the 'pessimistic' outcome
- ◆ Thus, the results are presented both cautiously (the 'pessimistic' figures) and pragmatically (the 'optimistic' figures).

Litigation and complaints

Each reporter was asked to state whether the patient was pursuing litigation as a result of the complication.

Remediable aspects of care

The review panel assessed each case to determine whether remedial care was present.

Validation of data

Requests were made to several organisations for information which might validate (i.e confirm the completeness of) both denominator and numerator data. For the denominator this included the National Joint Registry, the National Obstetric Anaesthesia Database and the Department of Health Hospital Episodes Statistics. For the numerator we sought evidence of relevant cases from the NHS Litigation Authority (NHSLA) and National Reporting and Learning Service (NRLS) of the NPSA, the Medical Protection Society and the Medical Defence Union. Medical journals were checked for reports of relevant cases and authors contacted as necessary. The internet search engine 'Google' was used to search for news items published on the internet with the words (epidural, spinal, death, abscess, haematoma, infection).

Incidence calculations

Cases were included in the numerator where a complication of CNB led to permanent patient harm and the CNB had been performed within the audit period and in an NHS hospital.

The data were entered into a Microsoft Excel 2007 spreadsheet (Microsoft Corporation, USA) and incidences were calculated (by dividing the numerator for a given group by the relevant denominator). Confidence intervals were derived using binomial probability tests with the stat-conf program (Handbook of Biological Statistics 2008, <http://udel.edu/~mcdonald/statconf.html>). The primary end points of the study were the incidences of permanent harm due to complications of the various types of CNB performed within the one year audit period

in an NHS hospital. These are presented in the next chapter as both 'pessimistic' and 'optimistic' incidences. The incidence of decompressive laminectomy in adult patients undergoing a perioperative epidural block was also calculated.

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CHAPTER 4: RESULTS



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This chapter is based on the results section of the paper published concurrently by the British Journal of Anaesthesia (Br J Anaesth, 2009: vol 102) and available through 'advance access' on the British Journal of Anaesthesia website (<http://bja.oxfordjournals.org>) from 12th January 2009.

HOSPITAL AGREEMENT TO PARTICIPATE

By September 2006 all 309 departments contacted by the project team had agreed to participate and had appointed a local reporter.

DENOMINATOR DATA (CENSUS RETURNS)

This data is a slightly different from that published previously because that was based on 97% return rates, which were correct at that time.¹ Subsequent to publication, a 100% return was obtained.

All hospitals who were invited to participate in the project returned census data. Thus, the denominator data used in the calculation of incidences of complications are based on returns from all the National Health Service (NHS) hospitals believed to be performing surgery. Summed results of the census phase of the project are presented as annualised figures, in table 1. Annualised figures were determined by multiplying all census returns by 25 (*see Chapter 3: Project methods*).

Overall, 92% of hospitals graded their census returns as 'accurate' and these returns suggest that a total of just over 700,000 central neuraxial blocks (CNB) are performed annually in the

UK NHS, approximately 325,000 of them (46%) spinals, 293,000 (41%) epidurals, 42,000 (6%) CSE and 47,000 (7%) caudals. The majority of CNB were performed for obstetric (45%) or perioperative care (44%) indications. None of the databases consulted in an attempt to validate these data provided information which could be used for that purpose.

NUMERATOR DATA (COMPLICATIONS REPORTED)

Event returns and validation of completeness

In total, 108 cases were reported directly to the project team or through the National Confidential Acute Pain Critical Incident Audit (NCAPCIA), with 84 of these being considered appropriate for panel review. The 24 cases eliminated by the project team prior to panel review were all minor complications of no relevance to the problems under consideration: when there was the slightest doubt the cases were included for review.

The NHS Litigation authority (NHSLA) and National Reporting and Learning System (NRLS) databases were screened by the National Patient

	Perioperative	Obstetric	Chronic pain	Paediatric	Non-anaesthetists	Totals: block types
Epidural	97,925	161,550	27,975	3,125	2,475	293,050 (41.4)
Spinal	189,000	133,525	1,325	325	775	324,950 (46)
CSE	16,525	25,350	0	0	0	41,875 (5.9)
Caudal	9,000	0	11,375	18,050	9,125	47,550 (6.7)
Totals:	312,450 (44.2)	320,425 (45.3)	40,675 (5.7)	21,500 (3.0)	12,375 (1.7)	707,425 (100)
indications						
Accurate replies	83%	95%	94%	91%	91%	92%

Table 1.

Census phase: estimate of the number of central neuraxial blocks procedures performed annually in 309 UK NHS hospitals (100% return). Figures in parentheses are percentages. 'Non-anaesthetists' include neurosurgeons, spinal surgeons, orthopaedic surgeons, rheumatologists, 'physicians' and general practitioners. The bottom row indicates the percentage of returns recorded as 'accurate': others were close estimates, or estimates.

safety Agency (NPSA) for reports relating to CNB performed in the audit period. Approximately 1700 cases were reported to the NRLS (13 with a serious or fatal outcome) and five to the NHSLA. The audit lead (TC) reviewed an unselected subset of 200 of the NRLS cases, all NRLS cases with a serious or fatal outcome, and all NHSLA cases. The NRLS review identified only one case meeting the audit criteria (which was in the 13 serious cases): this had already been reported. Two NHSLA cases were potentially relevant. One (a wrong route injection error) clearly met the project inclusion criteria, but did not match the details of any case reported to this audit at that time. A second case (of nerve injury) possibly met the inclusion criteria, but it was not clear whether it had been reported or not. Both hospitals were contacted by the NPSA and asked to report the case if it met inclusion criteria and had not been reported already. The wrong route injection case was subsequently reported to NCAPCIA and is included with those reviewed in detail.

Review of the literature identified three potential cases for inclusion, but discussion with the authors of the papers indicated that they did not meet the criteria. Internet based news 'alerts' identified the wrong route injection case also identified by NHSLA screening. Other sources of validation did not identify any further cases.

Sources and timing of reports

Although the methodology of the process meant that anonymous reporting was possible, the majority (67) of cases were from identified individuals: 56 anaesthetists, nine neurologists and two acute pain nurses. Similarly, other details cannot be described in full, but reports were received from all areas of the UK. Four hospitals reported more than one event, but two of these had neurosurgical units and were reporting complications of CNBs which had been performed elsewhere. It was not possible to obtain detailed information about the dual reports from the other two hospitals.

Events were notified throughout the audit period, but only one was reported after December 2007 and that was in August 2008, five months after the formal closure date. However, review indicated that it should be included in the analysis, even at a late stage.

Review panel assessments

Eighty four cases were reviewed and 52 were found to meet all of the audit's inclusion criteria (Table 2). Reasons for exclusion included incorrect diagnosis, minor complication, date outside the review period and procedure not performed in an NHS hospital. All 84 were reviewed for learning points (*see Section 2: Chapters 6–18*) but the remaining 52 are the focus of this analysis. Of these 52 patients 22 made a documented

Category	Total	Excluded from incidence calculation: full recovery	Included: pessimistic incidence calculation	Included: Optimistic incidence calculations
Epidural Abscess	20	7	8	3
Meningitis	6	3	0	0
Vertebral canal haematoma	8	1	5	4
Nerve injury	18	7	7	3
Spinal cord ischaemia	6	0	4	0
Wrong route error	11	8	1	1
Cardiovascular collapse	6	3	3	2
Miscellaneous	9	1	2	1
TOTAL	84	30	30	14

Table 2:

Summary of cases reviewed and their classification by review panel. Exclusion from review was due to wrong diagnosis, minor injury, procedure performed outside the dates of the audit or in a non-NHS hospital. See text for definitions of 'pessimistic' and 'optimistic' categories.

	Cases included n=52	Cases with permanent injury (pessimistic interpretation), n=30	Cases with permanent injury (optimistic interpretation), n=14
Gender			
Female : male	33 : 19	17 : 13	7 : 7
Age in years			
<16	0	0	0
16–50	16	8	3
51–70	17	9	5
>70	19	13	6
ASA grade*			
1–2	33	16	8
3–4	17	13	5
Not assessed	2	1	1
Surgery			
Major : not major : none	33 : 11 : 8	21 : 5 : 4	10 : 2 : 2
Elective : emergency (total operations)	33 : 11 (44)	21 : 5 (26)	11 : 1 (12)
Site of nursing:			
Ward : ICU: died in theatre	11 : 34 : 2	16 : 10 : 2	10 : 2 : 1
Not recorded	5	2	1
Operator for procedure**			
Consultant	27	15	7
Non-consultant-career grade	6	4	2
Specialist registrar	5	3	1
Senior house officer	4	2	0
Not recorded	10	6	4

Table 3.

Demographic data of cases reviewed by panel. See text for definitions of 'pessimistic' and 'optimistic' categories.

*Based on reporter's data with some interpretation

**Not all data were requested for groups of complications (e.g. operator details were not requested for cardiovascular collapse, wrong route errors or miscellany).

	Cases	Epidural / Spinal / CSE / Caudal	Perioperative / Obstetric / Chronic pain / paediatrics / non-anaesthetist
Epidural Abscess	8	5 / 2 / 0 / 1	6 / 1 / 1 / 0 / 0
Meningitis	0	0 / 0 / 0 / 0	0 / 0 / 0 / 0 / 0
Vertebral canal haematoma	5	5 / 0 / 0 / 0	5 / 0 / 0 / 0 / 0
Nerve injury	7	3 / 3 / 1 / 0	5 / 2 / 0 / 0 / 0
Spinal cord infarction	4	4 / 0 / 0 / 0	4 / 0 / 0 / 0 / 0
Wrong route	1	0 / 0 / 1 / 0	1 / 0 / 0 / 0 / 0
Cardiovascular collapse	3	0 / 2 / 1 / 0	3 / 0 / 0 / 0 / 0
Miscellaneous	2	1 / 0 / 1 / 0	1 / 1 / 0 / 0 / 0
TOTAL	30	18 / 7 / 4 / 1	25 / 4 / 1 / 0 / 0

Table 4. Complications used in calculation of 'pessimistic' (see text for explanation) incidences related to type of block and clinical indication.

complete recovery from their serious complication (NPSA classification 'moderate';² see *Chapter 3: Project methods, table 2*): seven vertebral canal abscesses, seven nerve or spinal cord injuries, three cardiovascular collapses (requiring cardiopulmonary resuscitation or admission to intensive care), three cases of infective meningitis, one vertebral canal haematoma and one other (intrathecal opioid overdose leading to respiratory arrest). These cases are not considered further in the calculation of incidence of harm.

The remaining 30 events were used in the calculation of the 'pessimistic' incidences of permanent harm after CNB techniques. Detailed review indicated that in 16 of these the patients were either likely to make a good recovery or the attribution of the permanent harm to the block was tenuous. This left 14 events for the calculation of the 'optimistic' incidences.

The full classifications of all 84 cases classified by complication, indication and type of CNB are presented in *Appendix 4*.

Demographics

Events were distributed across both genders and the range of ASA status, with the majority of events occurring after elective surgical procedures and about half the CNBs having been performed by consultants and half by other grades (table 3). There were no children in the 52 patients in the audit, and the majority of cases occurred in patients aged over 50 years. In the 30 patients with permanent harm (judged 'pessimistically') the complications occurred after all types of CNB:

- ◆ 18 (60%) epidural block
- ◆ 7 (23%) spinal anaesthesia
- ◆ 4 (13%) CSE and
- ◆ 1 (3%) Caudal

As far as clinical indication was concerned, 25 (83%) were in the perioperative group (Table 4).

	Perioperative	Obstetric	Chronic pain	Paediatric	Non-anaesthetists	Sum
Epidural	17.4 (7.2–27.8)	0.6 (0–3.4)	0 (0–10.7)	0 (0–95.9)	0 (0–121.1)	6.1 (3.6–9.7)
Spinal	2.6 (1.0–6.2)	1.5 (1.0–5.4)	0 (0–226.1)	0 (0–921.8)	0 (0–386.6)	2.2 (1.0–4.4)
CSE	18.2 (3.7–53.0)	3.9 (1.0–22.0)	n/a	n/a	n/a	9.6 (2.6–24.5)
Caudal	0 (0–33.3)	n/a	8.8 (1.0–49.0)	0 (0–16.6)	0 (0–32.8)	2.1 (1.0–11.7)
Total	8.0 (5.2–11.8)	1.2 (1.0–3.2)	2.5 (1.0–13.7)	0 (0–13.9)	0 (0–24.2)	4.2 (2.9–6.1)

Table 5. Incidence of permanent harm after central neuraxial block with 'pessimistic' (see text for explanation) interpretation of data: events per 100,000 cases (95% confidence interval). n/a = zero denominator (i.e. no cases reported in this group in the 'snapshot' phase of the project).

	Perioperative	Obstetric	Chronic pain	Paediatric	Non-anaesthetists	Sum
Epidural	8.2 (3.5–16.1)	0.6 (0–3.4)	0 (0–10.7)	0 (0–95.9)	0 (0–121.1)	3.1 (1.4–5.8)
Spinal	1.6 (1.0–4.6)	0 (0–2.2)	0 (0–226.1)	0 (0–921.8)	0 (0–386.6)	0.9 (0–2.7)
CSE	12.1 (1.5–43.7)	0 (0–11.8)	n/a	n/a	n/a	4.8 (1.0–17.3)
Caudal	0 (0–33.3)	n/a	0 (0–26.3)	0 (0–16.6)	0 (0–32.8)	0 (0–6.3)
Total	4.2 (2.2–7.1)	0.3 (0–1.7)	0 (0–7.4)	0 (0–13.9)	0 (0–24.2)	2.0 (1.1–3.3)

Table 6. Incidence of permanent harm after central neuraxial block with ‘optimistic’ (see text for explanation) interpretation of data: events per 100,000 cases (95% confidence interval).

n/a = zero denominator (ie no cases reported in this group in the ‘snapshot’ phase of the project).

Incidence of permanent harm

Considering the overall totals first, the incidence of any permanent injury (NPSA classifications serious and fatal,² see *Chapter 3: Project methods, table 2*) after all CNBs in this series is 4.2 in 100,000 (95% Confidence interval 2.9–6.1; equivalent to 1 in 23,500) using the ‘pessimistic’ assessment of outcome, and 2.0 in 100,000 (95% CI 1.1–3.3; 1 in 50,500) using the ‘optimistic’ assessment. However, there was considerable variation between the incidences after different types of block. In both ‘pessimistic’ and ‘optimistic’ assessments, epidural and CSE were associated with higher incidences than both spinal and caudal block. Looking at clinical indication also revealed similar variation.

By using the subgroups we used in the census phase (table 1) it is possible to calculate incidences for each of the subgroups. We report these for completeness (tables 5–8), but caution against their over-interpretation (see next chapter). The incidence of complications was highest after perioperative use and considerably lower in other groups (tables 5 and 6). The incidence of permanent injury after adult perioperative epidural anaesthesia or analgesia was ‘pessimistically’ 17.4 in 100,000 (95% CI 7.2–27.8; 1 in 5,700) and ‘optimistically’ 8.2 per 100,000 (95% CI 3.5–16.1; 1 in 12,200). Twelve patients in this category underwent decompressive laminectomy (seven for abscess, four for vertebral canal haematoma and one

	Perioperative	Obstetric	Chronic pain	Paediatric	Non-anaesthetists	Sum
Epidural	6.1 (2.2–13.3)	0 (0–1.9)	0 (0–10.7)	0 (0–95.9)	0 (0–121.1)	2.0 (1.0–4.5)
Spinal	2.1 (1.0–5.4)	0 (0–2.2)	0 (0–226.1)	0 (0–921.8)	0 (0–386.6)	1.2 (1.0–3.2)
CSE	12.1 (1.5–43.7)	0 (0–11.8)	n/a	n/a	n/a	4.8 (1.0–17.3)
Caudal	0 (0–33.3)	n/a	8.8 (1.0–49.0)	0 (0–16.6)	0 (0–32.8)	2.1 (1.0–11.7)
Total	3.8 (2.0–6.7)	0 (0–0.9)	2.5 (1.0–13.7)	0 (0–13.9)	0 (0–24.2)	1.8 (1.0–3.1)

Table 7. Incidence of paraplegia or death after central neuraxial block with ‘pessimistic’ (see text for explanation) interpretation of data: events per 100,000 (95% confidence interval).

n/a = zero denominator (i.e. no cases reported in this group in the ‘snapshot’ phase of the project).

	Perioperative	Obstetric	Chronic pain	Paediatric	Non-anaesthetists	Sum
Epidural	1.0 (1.0–5.7)	0 (0–1.9)	0 (0–10.7)	0 (0–95.9)	0 (0–121.1)	0.3 (0–1.9)
Spinal	1.1 (1.0–3.8)	0 (0–2.2)	0 (0–226.1)	0 (0–921.8)	0 (0–386.6)	0.6 (0–2.2)
CSE	12.1 (1.5–43.7)	0 (0–11.8)	n/a	n/a	n/a	4.8 (1.0–17.3)
Caudal	0 (0–33.3)	n/a	0 (0–26.3)	0 (0–16.6)	0 (0–32.8)	0 (0–6.3)
Total	1.6 (1.0–3.7)	0 (0–0.9)	0 (0–7.4)	0 (0–13.9)	0 (0–24.2)	0.7 (0–1.6)

Table 8. Incidence of paraplegia or death after central neuraxial block with ‘optimistic’ (see text for explanation) interpretation of data: events per 100,000 (95% confidence interval).

n/a = zero denominator (i.e. no cases reported in this group in the ‘snapshot phase’ of the project).

Table 9. Case summaries of deaths due to CNB.

Death 1
<p>A middle aged patient with locally advanced and metastatic malignancy underwent a very prolonged urological procedure under spinal anaesthetic. No senior anaesthetist was present. Moderate hypotension progressed to profound hypotension with no recordable blood pressure. Attempted resuscitation, involving senior members of staff, was unsuccessful. The death certificate recorded acute myocardial infarction as the cause of death. The case was included in the pessimistic and optimistic incidences and death was considered a direct complication of CNB. (See Chapter 12: Cardiovascular collapse)</p>
Death 2
<p>A very elderly frail patient had a joint arthroplasty performed under CSE and was nursed on ICU postoperatively. During a period of hypotension a large volume of bupivacaine was inadvertently administered intravenously. The patient developed pulseless electrical activity and prolonged resuscitation failed. An inquest recorded a verdict of accidental death. The case was included in the pessimistic and the optimistic incidence of permanent harm. Death was considered a direct complication of CNB. (See Chapter 11: Wrong route administration)</p>
Death 3
<p>A healthy elderly patient underwent a lower limb arthroplasty. The epidural component of a CSE was complicated by an inadvertent dural tap. Anaesthesia was uneventful. A low dose local anaesthetic infusion was commenced via the epidural catheter and several hours later the patient was found in cardiac arrest. Routine observations had not been performed for several hours. The patient was resuscitated and admitted to ICU, but major neurological damage was evident and the patient died several weeks later. The case was included in the pessimistic and optimistic incidence and death was considered a direct complication of CNB. (See Chapter 12: Cardiovascular collapse)</p>
Death 4
<p>An unfit elderly patient was due to undergo repair of a fractured neck of femur. Spinal anaesthesia was performed. Approximately 12 minutes later the patient collapsed and resuscitation was unsuccessful. Information on this case was grossly incomplete. There was also uncertainty as to what lead to the patient's death: potential causes included drug allergy, thromboembolic or fat embolus as well as complications related to the spinal anaesthetic. The case was included in the pessimistic incidence and excluded from the optimistic incidence. Death was considered a direct complication of CNB. (See Chapter 12: Cardiovascular collapse)</p>
Death 5
<p>An elderly unfit patient underwent a caudal injection for chronic back pain. Recovery was uneventful. Several days later the patient presented with sepsis and a vertebral canal abscess (distant from the procedure site) was identified. 'Unrelated complications during hospital admission' lead to ICU admission. The patient made a good recovery from these but then suffered an unexpected fatal cardiac arrest. The chain of events that culminated in patient death started with the caudal block, but the chain of causation is far from clear. The case was included in the pessimistic and excluded from the optimistic incidence of permanent harm. Death was considered an indirect complication of CNB. (See Chapter 8: Vertebral canal abscess)</p>
Death 6
<p>An elderly patient with multiple medical co-morbidities and immunosuppression was admitted to intensive care (ICU) after a respiratory arrest. The patient had vertebral collapse and uncontrollable back pain. Use of parenteral opioid analgesia prior to ICU admission had lead to pneumonia and respiratory arrest. After discussion, an epidural was inserted leading to good analgesia. Within 24 hours the patient developed leg weakness and subsequent investigation identified a vertebral canal abscess. Surgery was offered and declined. The patient developed paraplegia and was discharged, wheelchair-bound, at 6 months. The patient died an indeterminate period of time later. There was doubt as to whether the abscess pre-existed the epidural. There was also uncertainty as to what lead to the patient's death. The case was included in the pessimistic incidence and excluded from the optimistic incidence. Death was considered an indirect complication of CNB. (See Chapter 8: Vertebral canal abscess)</p>

	Cases reported with initial neurological impairment	Major improvement	No or minimal improvement
Ischaemia	5	0 (0)	5 (100)
Abscess	12	7 (58)	5 (42)
Nerve injury	13	9 (69)	4 (31)
Meningitis	3	3 (100)	0 (0)
Vertebral canal haematoma	8	6 (75)	2 (25)
TOTAL	41	25 (61)	16 (39)

Table 10. Prognosis, at 6 months, of all significant injuries with early neurological injury after CNB: numbers (percentage). Cases include those occurring following CNB performed outside the audit period or in non-NHS hospitals. Immediately fatal cases are not included.

as a result of nerve injury in association with spinal stenosis), an incidence of 12.3 in 100,000 cases (95% CI 6.3–21.4). One patient declined laminectomy.

Paraplegia and death are the worst possible outcomes so figures for these (13 ‘pessimistic’ and 5 ‘optimistic’) were extracted and analysed in the same way. The overall incidence of these two complications in this series is ‘pessimistically’ 1.8 in 100,000 (95% CI 1.0–3.1; 1 in 54,500) and ‘optimistically’ 0.7 in 100,000 (95% CI 0–1.6; 1 in 141,500) (tables 7 and 8). The patterns revealed are similar to those seen in the analysis of all permanent complications.

Six patient deaths were reported (two vertebral canal abscesses, three cardiovascular collapses, one wrong route error). All were included in the ‘pessimistic’ assessment, giving a rate of less than 1 in 100,000 (0.8 in 100,000: 95% CI 0–1.8), and three in the ‘optimistic’ group, a rate of less than 1 in 200,000 (0.4 in 100,000: 95% CI 0–1.2). Four of the deaths were considered to be directly associated with CNB and two indirectly.

Consideration of the cases with a fatal outcome (table 9) may clarify how determinations of ‘pessimistic’ and ‘optimistic’ decisions were made, and illustrate the need to present the outcome data in both ways.

Table 10 records the progress of those patients reported to NAP3 with an initially serious neurological injury in whom we were able to determine a final outcome. Patients are included even if they did not meet inclusion

criteria (e.g. incidents occurring outside the audit dates or in private hospitals).

Litigation and complaints

When a case was reported to NCAPCIA one of the questions asked was whether litigation was in progress or planned as a result of the complication. Of the 52 reports of initially major complications only 28 replies were obtained. In 25 cases the LR indicated that no litigation or complaint was in progress or expected. In two cases litigation was in progress (one cardiovascular collapse and one direct spinal cord injury) and in one case a formal complaint had been made.

Remediable care

The review panel assessed each of the 52 cases that were fully reviewed to determine whether there was evidence of remediable care. Remediable care might be individual or organisational. In eight the consensus was that there were clear elements of remediable care and in 32 there was consensus that no evidence of remediable care existed. In 12 there was inadequate information to enable a judgement.

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NAP 3

Report and findings of the 3rd National Audit
Project of the Royal College of Anaesthetists

CHAPTER 5: DISCUSSION



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This chapter is based on the discussion section of the paper published concurrently by the British Journal of Anaesthesia (Br J Anaesth, 2009: vol 102) and available through 'advance access' on the British Journal of Anaesthesia website (<http://bjaoxfordjournals.org>) from 12th January 2009.

This project is possibly the largest prospective study of central neuraxial blocks (CNB) and its major complications that has been reported. The results are largely reassuring with the incidence of permanent injury being lower than in other equivalent or related studies.¹⁻⁶ Assessed 'pessimistically' the incidence of permanent injury after CNB was 4.2 in 100,000, and of paraplegia/death was 1.8 in 100,000. 'Optimistically' the incidence of permanent injury was 2.0 in 100,000 and of paraplegia/death 0.7 in 100,000. The incidence of complications of epidural and combined spinal epidural (CSE) were at least twice those of spinal and caudals.

Previous studies have focused on the neurological complications of CNB, but this project took a broader approach and included all major complications of CNB, whether leading to neurological or other major sequelae. As a result several deaths and major complications from wrong route errors (*see Chapter 11: Wrong*

route administration) or cardiovascular collapse (*see Chapter 12: Cardiovascular collapse*) were identified that would otherwise have been missed, so that this is a more 'complete' evaluation than many previous studies.

An internal NPSA paper describes epidural anaesthesia and its multiple potential complications well: 'a complex amalgam of clinical judgment, technical skills, materials and equipment, drug delivery systems, patient supervision and care pathways. In addition to inherent complications in the procedure, each of these facets has the potential to generate patient harm through a combination of patient characteristics, human error or shortfalls in performance, equipment dysfunction and broader system failures. As a consequence, an enormous number of injuries can result.'⁷ This description is applicable to all forms of CNB and encapsulates the complexity of these seemingly simple procedures. The results of this national project reflect the complexities of both CNB and the interpretation of its sequelae.

Data interpretation

The data contain both clinical uncertainty and statistical uncertainty.

We have presented the results in both 'pessimistic' and 'optimistic' terms to acknowledge the clinical uncertainty. As the case descriptions of the patients who died (*see Chapter 4: Results*) illustrate, in many cases interpretation of clinical descriptions was difficult because causation may be uncertain within a complex train of events. In other cases the degree to which CNB led to final outcome may be uncertain. Throughout *Section 2* of this report each chapter contains vignettes describing cases (*Chapters 6–18*). While detail is limited, because of limited space and the need for anonymity, these enable the reader to consider some of the difficulty of deciding causation and association. Not all readers will agree with the interpretation of all these cases, but use of the pessimistic and optimistic interpretations goes some way to accommodating differences of opinion that also existed in the review panel. As an example we do not know whether spinal cord ischaemia after general anaesthesia in elderly frail patients who also have an epidural in place is caused by the CNB or simply co-incidental: there were four such cases. Further, the final outcome was not always clear. One option would have been to be more decisive and simply present one 'best guess' result, but this would be an inappropriately simplistic response to the reality of complex clinical data. In 11 of 84 cases interpretation was hampered by incomplete information: gaps were interpreted pessimistically even though this may mean that some patients were included inappropriately.

Statistical uncertainty is accommodated by the use of 95% confidence intervals for all calculated incidences both in the preceding chapter and in the clinical reviews of *Section 2* of this report. In many cases confidence intervals are large, an inevitable consequence of the low or zero numerators of some groups. The data with

the narrowest confidence intervals are those with larger numerators and large denominators. Data with low or zero numerators are notoriously difficult to interpret.^{8,9} For zero numerators we used the recommended 'rule of 3' (which states that for n observations with a zero numerator the upper 95% confidence limit is $3/n$) to calculate the upper confidence limit.⁸ The importance of this is that the main results have quite narrow confidence intervals (e.g. pessimistic incidence of permanent injury from any CNB; 4.2 in 100,000 cases, 95% confidence interval 2.9–6.1). In contrast some of the sub-classifications of the data have very wide confidence intervals (e.g. optimistic incidence of death or paraplegia after spinal anaesthesia in children 0 in 100,000 cases, 95% confidence interval 0–922). This makes such data, particularly those with zero numerators, very difficult to interpret, and we would advise extreme caution in so doing.

In *Section 2* of the report each chapter contains a section 'Quantitative aspects' that examines the incidence of complications and of permanent harm for the clinical area under consideration. These subdivisions contain necessarily smaller denominators than the overall results and often small numerators. Again caution is advised in interpreting these data and readers should consider not only the point estimates but also the confidence intervals.

The nature of this project means that whatever incidences are calculated from our data, these can only be minimum incidences: cases which were not reported or were wrongly excluded from our analysis would obviously increase the rates. With a numerator of 30, each additional case would increase the overall pessimistic incidence by approximately 3%.

Data reliability and validation

The first and most obvious question is, 'are the results robust?' We consider the denominator(s) to be extremely robust because they are based on a census of activity of the entire relevant

population; not a sample of that population. All the relevant United Kingdom (UK) hospitals committed to the project and the census return rate was 100%, with over 92% of these data being reported as 'accurate'. Therefore any error in the denominator is small. Variations in the accuracy of denominators are discussed in individual chapters where this is relevant.

Within the numerator data there are both 'known unknowns' and 'unknown unknowns'.¹⁰

The known unknowns are those cases which were reported, but where the detail was inadequate for robust decisions on the nature or the outcome of the event. In 11 cases (13%) there was insufficient information to determine the patient's long term outcome, so in each it was assumed that no recovery took place beyond the last indicated clinical condition. As a result several cases have been classified 'pessimistically' as suffering permanent injury when it is very possible that full recovery occurred: this will have increased the incidence of such complications in the results

The unknown unknowns are those cases which may exist, but were not notified and therefore have not been included in the calculations of incidences. It is inevitably impossible to determine their number and futile to speculate on how many cases have not been reported, but every effort was made to ensure that information about the project was disseminated as widely as possible, both within and outwith the anaesthetic specialty. That 100% of hospitals volunteered a local reporter to the project, 100% returned snapshot data and more than 10% of cases were notified by non-anaesthetists attests to the wide awareness and enthusiasm for the project.

A number of sources were searched in an effort to validate the denominator (the number of procedures performed annually) and numerator (the number of relevant complications). These sources were either incomplete, did not match

the population surveyed, were not validated themselves, or were impossible to correlate with the data presented here. It is reassuring that none of the sources searched provided any information which conflicted with this project's data and was, in large part, consistent with it. During this attempt at validation it became apparent that most cases of significant injury after CNB had not been notified to other national databases of clinical incident (e.g. the National Reporting and Learning Service, NRLS). This raises concerns over the current under-reporting of serious clinical incidents to the NRLS. It is, however, recognised that a number of data sources are required to fully capture and characterise clinical incidents.¹¹ In contrast validation attempts only identified one case that had, at that time, not been reported to us and we subsequently learned of this case by other means also.

In spite of the inability to validate data externally, comparisons may be made with other data published recently. A UK wide audit of over 10,000 paediatric epidurals performed between 2001 and 2005 reported a similarly low number of major complications, no deaths and an incidence of permanent neurological injury of 1 in 10,663¹² and thus is consistent with this survey (also see *Chapter 18: Paediatrics*). A very recent survey (with an 84% response rate) of UK hospitals by Meikle and colleagues, indicated that respondents had knowledge of 40 vertebral canal haematomas occurring in a 6 year period.¹³ During this current project a number of reports were received about cases of major injury which, when details were sought, were found not to meet the inclusion criteria so it is difficult to judge how robust are the anecdotal and retrospective data included in Meikle and colleagues' survey. However, their annual rate of seven cases per year is very similar to that of this project: eight cases of vertebral canal haematoma were reported in one year, with five meeting full inclusion criteria (see *Chapter 7: Vertebral canal haematoma*).



Perioperative epidurals were associated with more major complications and permanent harm than CNB of other types and for other indications

In a recent Canadian series the rate of decompressive laminectomy was 21 in 100,000 cases.¹⁴ In an equivalent sub-group (adult, non-obstetric perioperative epidurals) from the data reported here the point estimate of the incidence of decompressive laminectomy was 12.3 in 100,000, a rate that is within the confidence limits of the Canadian data. In interpreting these figures it should be noted that Canadian and UK practice in selecting patients for laminectomy may well differ. In our cohort there are nine cases who did not undergo laminectomy but might have if the threshold for its performance was lower. Against this background it is interesting to note that the rate of laminectomy in the Canadian study did not differ significantly between those patients who did, or did not receive epidural analgesia.

Comparison with other studies

The burden of neurological complications from CNB compared to other causes such as general anaesthesia and surgery is not well reported. A recent review of 54 cases from a UK medical defence organisation found that 72% were 'surgical' and 28% 'non-surgical'.¹⁵ Of the non-surgical cases half were judged to be due to needle injury, and this included 'epidural, intravenous and intramuscular injections'. While

the numbers involved are small, and the analysis of cases very limited, the report indicates that neurological injury associated with regional anaesthesia is much less frequent than that related to surgery. Further, while the nature of injuries differs, the incidence of nerve injury attributed to anaesthesia differs little between regional and general techniques, an observation reported previously.¹⁶

The best information available previously on major complications after regional anaesthesia comes from surveys in two Scandinavian countries, Finland and Sweden, both having 'no fault' compensation schemes and populations small enough to allow central reporting systems. In Finland, a survey of 720,000 procedures performed between 1987 and 1993 found that the incidence of major complications was 1 in 22,000 after spinal anaesthesia and 1 in 19,000 after epidural block.² In Sweden, a survey of 1.7 million procedures performed between 1990 and 1999 found an incidence of severe neurological complications of 1 in 20–30,000 after spinal anaesthesia, 1 in 25,000 after obstetric epidural and 1 in 3,600 after non-obstetric epidural.³ Both reviews were retrospective.

In the UK, Christie and colleagues recorded, using a retrospective methodology, 12 major complications after 8,100 perioperative epidurals (1 in 675) administered over a 6 year period in one hospital.⁵ This approximates to 148 in 100,000 epidurals, but nine patients made a full recovery so the incidence of permanent injury was three in 8,100 (37 in 100,000, 95% CI 7.6–108). Our point estimates for adult permanent injury after perioperative epidural are: pessimistic 17.4 in 100,000 (95% CI 7.2–27.8) and optimistic 8.2 in 100,000 (95% CI 3.5–16). While the confidence intervals from these data are narrower than those of Christie and colleagues, there is considerable overlap. The figures reported here come from a population some 12 times larger than Christie's so that point estimates and confidence intervals are likely to be more robust.

Cameron and colleagues reported a similar, retrospective, single hospital series, from Australia.⁶ Two vertebral canal haematomas and six epidural abscesses followed 8,210 'acute pain' epidurals performed between 1990 and 2006. One laminectomy was required and there were no cases of permanent neurological injury. Converting these to incidences as presented here gives a vertebral canal haematoma rate of 24 in 100,000 (95% CI 3–88), an abscess rate of 73 in 100,000 (95% CI 27–159), a laminectomy rate of 12 in 100,000 (95% CI 1–68) and an incidence of permanent neurological harm of 0 in 100,000 (95% CI 0–45), figures which are again broadly consistent with those reported here.

Clinical implications

In the current series, as in the Swedish study, most complications of CNB were found to occur when epidural block was used in the perioperative period. Whether this was because it was used in the higher risk patients is not something that this project can identify, but a higher (or lower) incidence of complications in one sub-group does not necessarily equate to the procedure being less (or more) appropriate for them. There are both statistical and clinical reasons for this. First, Moen and colleagues' figure of 1 in 1,800 major complications in women having epidural anaesthesia for knee arthroplasty is often quoted,³ but the absence of any complications in men having the same procedure for hip arthroplasty or spinal anaesthetic for knee arthroplasty is rarely mentioned. In that study the denominators for these groups were as low as 7,000 and thus are too small for robust point estimates of incidences of complications, with random effects potentially leading to apparently high or low incidences. Equally, the data from the smaller sub-groups reported here will be less reliable.

Second, the clinical perspective of the appropriateness or safety of a CNB procedure must also recognise both the potential benefits of that procedure (compared to other techniques) and risks other than the major ones reported here. Risk benefit analysis might

therefore consider CNB efficacy and reliability, its potential to improved outcomes, complications consequent on omission of CNB, complications of alternatives to CNB and also other risks both of CNB and of alternative treatments. Such risk-benefit analyses will differ between subgroups of patients and procedures so, for both statistical and clinical reasons, comparisons between sub-groups should be made with considerable caution.

The demographics of the patients in this report are also relevant. More complications were reported in females than males, but permanent injury was equally frequent in both. While many patients experiencing complications were aged over 70 a significant proportion were aged below 50 years of age (*see Chapter 4: Results, table 3*). More than half of the patients were fit and well (estimated ASA grade 1–2), and most patients were undergoing major, elective surgery with CNB being performed by consultants. However, denominator data for these observations were not collected, so it is impossible determine whether, or to what extent, these factors are associated with, let alone causal of, adverse outcomes. Despite this, some subgroup findings are of interest: patients who developed spinal cord ischaemia, vertebral canal haematoma and vertebral canal abscess were usually elderly, many were infirm and most undergoing major surgery. In contrast patients suffering (non-ischaemic) nerve injury were more likely to be young and healthy. These differences again imply that direct comparisons between sub-groups should only be made with extreme caution. Each of these topics is discussed in greater detail in *Section 2*.

Accepting these cautions, several clinical findings are of note. More complications leading to permanent harm occurred in the perioperative epidural group than in any other sub-group although notably, all four perioperative deaths occurred in association with spinal or CSE block. Obstetric, chronic pain and paediatric groups had a low incidence of major complications. This series includes one

of the largest cohorts of each sub-group and, as such, those results are reassuring. Again each of these subgroups is discussed in greater detail in *Section 2*.

Concerns have been raised previously about the safety of CSE,^{17–19} and in this series it had a relatively high incidence of complications. It represented only 5.9% of all CNBs performed, but led to 13–14% of permanent injuries and 15–40% of cases of paraplegia/death. Two of the deaths followed its use (see *Chapter 14: Perioperative*).

Of perhaps greater concern is the continuing problem with ‘wrong route’ administration errors: nine cases are reported here, six in obstetric practice. There was one death, but no other patient came to permanent harm. A further death (from intravenous bupivacaine) occurred in an obstetric unit a short while before this audit started,²⁰ and the coroner judged the institution responsible for the patient’s care to be guilty of an ‘unlawful killing’.²¹ Since that event the National Patient Safety Agency (NPSA) has published a safety alert highlighting the problem and identifying measures to reduce it,²² and multi-professional guidance on best practice has also been published.²³ That one in four respondents to a recent survey of 206 UK obstetric units reported knowledge of such an event indicates that this remains a major problem.²⁴ Several alternatives, to remedy these potentially fatal mix-ups, have been suggested or developed, but until such time as a robust solution is universally in place these events are likely to continue. This might be termed a national ‘systems error’. It is beyond the remit of this review to evaluate solutions, but clearly one must be found. This subject is discussed in *Chapter 11: Wrong route administration*.

Prognosis of neurological complications

Most reviews of serious complications of CNB do not report their prognosis. All major complications are important, but the most critical outcome for both clinicians and patients

is the incidence of permanent harm. As noted above, the figure of one major complication for every 675 perioperative epidurals in the study by Christie and colleagues received much attention, but the fact that 9 of 12 the patients made a full recovery did not. In this project it was possible to monitor the progress of 41 major complications which led initially to serious neurological injury (*Chapter 4: Results, table 10*), and in 25 (61%) complete, or almost complete, recovery was documented.

Within sub-groups the recovery rates did vary: neurological injury associated with spinal cord ischaemia or vertebral canal haematoma had a notably poor prognosis, while all patients affected by meningitis recovered fully, as did the majority of patients experiencing nerve injury and abscess. It is important to note that we did not set out to identify all mild or moderate complications of CNB, so unreported minor cases will have occurred in some categories and some may have resulted in permanent harm.

Litigation and complaints

Local reporters indicated that at the time of final reporting of each complication in almost 90% of cases (25 of 28) no litigation or complaint had been made or was expected. This data may not be robust, as complaints and litigation often occur many months or years after an event, but it is consistent with other reports that indicate that only a small minority of episodes of patient harm lead to litigation.^{25–29}

Remediable care

Retrospective review of cases is prone to interpretation error and bias as reviewers often differ in their interpretation of the same data³⁰ and there is evidence that the outcome of an event influences peer reviewers’ opinion (hindsight and outcome bias).^{31–33} In this series it is also likely that the panel did not have all the necessary data to form a completely robust opinion. Notwithstanding these limitations the review panel identified clear remediable care in only 20% of cases in which an opinion was offered. The implication is that harm

following CNB may occur even when care is of high quality. Based on the evidence in the cases reviewed, the effect of poor quality care is perhaps less to increase the number of complications than to lead to delays in diagnosis and treatment, often contributing to avoidable harm.

Overview

This project attempted to identify the incidence of major complications resulting in permanent harm after CNB in NHS hospitals in the UK. The number of such procedures was assessed in a two week review, and their complications were identified, followed up and analysed in detail, in a twelve month audit process. Analysis of the data suggests a lower incidence than reported previously in other series, usually of smaller numbers of patients, but there can be no certainty that all relevant cases were identified. It would need a significant number of additional cases for the results of this project to be changed significantly, but if anyone is aware of such an unreported case meeting the inclusion requirements (see *Chapter 3 : Project methods*) the review panel would welcome further reports (in confidence to Professor Wildsmith at jaww@doctors.org.uk). If a substantial number of reports is made the results will be updated in the future.

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