

NAP3: Safe as houses?

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The paper reporting NAP3 is in the British Journal of anaesthesia: Cook TM, Counsell D, Wildsmith JAW. Major complications of central neuraxial block: report on the Third National Audit Project of the Royal College of Anaesthetists. Br J Anaesth 2009; 102: 179–90). An editorial accompanies it [Buggy DJ. Editorial: central neuraxial block: defining the risk more clearly. Br J Anaesth 2009; 102: 151–3]. The full report of NAP3 is available as a free download at (<http://www.rcoa.ac.uk/index.asp?PageID=717>). All anaesthetists performing CNB should read it.

Background

The Royal College of Anaesthetists (RCoA) 3rd National Audit Project (NAP3) was set up to examine major complications of central neuraxial blockade. This is clearly an important topic to anaesthetists, and to patients. These major complications are rare, but just how rare is unclear. Reported incidences range from around 0.1% (100 per 100,000) to 0.001% (1 per 100,000) of procedures. Prior to NAP3 we did not have a robust estimate of the incidence of these major complications. Making communication of risk to patients difficult and also causing problems in balancing risk / benefit when selecting a patient's anaesthetic technique.

2004 was a bad year for epidurals in the UK. In May a nurse in a West Country hospital died soon after giving birth when an infusion bag of bupivacaine was inadvertently administered intravenously. This led the NPSA to publish a safety bulletin report (NPSA Safety Bulletin 21: Safer practice with epidural injections and infusions) [1] listing more than 10 required actions to increase the safety of storage and administration of drugs for epidural use. In addition the Royal College of anaesthetists and AAGBI both contributed to the publication of 'Good practice in the management of continuous epidural analgesia in the hospital setting' with more than 60 areas of good practice identified (RCoA 2004). In 2008 the inquest for that patient ruled the death was unlawful: further legal action may ensue [2]. In 2004 Lesley Ash, star of Men Behaving Badly, developed an epidural abscess following placement of a thoracic epidural for management of fractured ribs. Again in 2008 the NHS litigation authority (NHSLA) agreed a settlement with Lesley Ash's legal team of more than £5 million: almost three times the previous 'record' for anaesthesia related complications [3].

So were the planets in the wrong constellation in 2004? Was this bad luck? Are epidurals (and other central neuraxial blocks) safe or dangerous? If so are they acceptably risky? Anecdote is of limited use in answering this question.

The NHSLA database for 1995-2006 contains around 1000 cases with a little over 30% relating to regional anaesthesia. Although not all of these relate to central neuraxial block and although not all to neurological injury a substantial proportion do. The NHSLA dataset records a cost to the NHS of £11 million with 67% of claims costing the NHS money, a median payout of £4400 with a maximum of payout of £1.75 million (a haematoma following an epidural for bowel surgery).

With this in mind, what is the risk associated with central neuraxial blockade? The answer to this question is far from clear. Christie and colleagues published a paper in 2007 [4] reporting an incidence of epidural abscess following peri-operative epidural of 1 in 675. Of note 75% of patients made a full recovery. In contrast, also in 2007, a high quality prospective national audit of epidurals in paediatric anaesthetic practice reported only one case of neurological injury at 12 month follow up from more than 10,000 procedures [5]. Which do we believe, and what do we tell patients?

It is notoriously difficult to determine the incidence of infrequent events with any reliability. Some estimates are based on literature review. The literature on this subject is likely to suffer from publication bias. Christie's paper was not only published, but was also promoted by press release. Another author with a paper describing several thousand uncomplicated epidurals in the high-risk field of cardiac surgery could not find a journal willing to publish it (personal communication). Case reports and series lead to difficulty in using the literature to calculate incidences. Surveys and retrospective data trawls similarly suffer from incomplete acquisition and inaccurate memories.

The two best studies on the topic, prior to NAP3, are both Scandinavian. In both Finland and Sweden there is no fault compensation and all major complications occurring in hospital are reported to a central database. Two studies from these countries have both numerator and denominator data allowing calculation of an estimated incidence. Aromaa used a combination of a retrospective survey of all 83 departments in Finland to detect the incidence of major neurological complications from 1987-93 [6]. Each 'injured' patient was cross-referenced via their national insurance number with the national no fault insurance database. This was also used to identify further injured patients. Complications were defined similarly to complications in NAP3 (see below). Of 23,500 claims 86 (0.4%) were associated with central neuraxial blockade. The denominator was estimated from the national questionnaire: 550,000 spinals and 170,000 epidurals. There were 25 serious spinal-related complications and 9 serious epidural-related complications. The calculated incidence of serious complications was 1 in 22,000 following spinal and 1 in 19,000 following epidural. Moen used a similar methodology in Sweden (population 8 million) [7]. This in depth retrospective survey identified 1,260,000 spinals and 450,000 epidurals. Complication rates were spinal 1 in 20-30,000, epidural (non-obstetric) 1 in 3,600 and obstetric epidural 1 in 25,000. Almost 50% of cases were arachnoiditis and meningitis. The point estimates of risk suggest a high risk particularly with epidurals

in the female population (risk 1 in 4000). However it is certainly possible that some of this effect is random based on small numbers of numerators and denominators in sub-groups, leading to wide confidence intervals.

3rd National Audit Project

In 2005 the Royal College of Anaesthetists established the 3rd National Audit Project (NAP3) to determine both the number of central neuraxial procedures performed per year and the number of major complications, so establishing their incidence and prevalence. This will be the first prospective attempt to determine the prevalence and incidence of such complications.

The project had two phases.

First, for two weeks in September 2006 we conducted a snapshot survey of central neuraxial blocks (CNB) performed in UK NHS hospitals. Second, from September 1st 2006 and August 31st 2007 we sought to identify all major complications arising from CNB performed in the NHS. The data reporting window remained open until March 2008. The decision was made to only use data from procedures the NHS for calculating incidence of complications as it was deemed, rightly or wrongly, a more reliable source of data. Reports of complications would be accepted when the procedure was performed in the independent sector, but not included in incidence calculations.

The project was enormously widely support by NHS organisations. It was endorsed by all four Chief Medical Officers, the National Patient Safety Agency and each of the medical defence organisations. There was uniform support from all anaesthetic specialist societies invited to support (APA, OAA, BPS and RAGB&I) and from the AAGBI. In addition the specialist societies of the neurosurgeons (SBNS), spinal surgeons (BASS), neurologists (ABN) and radiologists (RCR, ABNR) all supported the project and actively promoted the project to their members.

The Central Office for Research Ethics Committee (COREC) agreed this audit did not require ethical approval. The Patient Information Advisory Group (PIAG, Department of Health), agreed the process.

The procedures from which complications were sought were

- Epidurals
- Spinals (subarachnoid block)
- Combined spinal epidurals (CSE)
- Caudal blocks

To include procedures in adults and children, and those performed by non-anaesthetists.

The complications sought were

- Serious infections (eg vertebral canal abscess, meningitis)
- Bleeding (eg vertebral canal haematoma)
- Major nerve damage (eg paraplegia, cord damage, cord infarction, major neuropathy)
- Death where the procedure is implicated
- All wrong route errors (intravenous drugs given epidurally/intrathecally or vice versa: whether associated with patient injury or not)

The outcome used for incidence calculation was also clearly defined: harm as a result of CNB persisting six months after the procedure. Thus in contrast to many previous studies which have focused almost entirely on neurological complications, NAP3 sought to identify 'all cause' harm after neuraxial block.

To support the project we established a network of 'local reporters' (LR) in every NHS anaesthetic department to co-ordinate the audit locally. Before starting the audit a LR was agreed in 100% of UK hospitals.

For the prospective phase we needed universal awareness of the project and to have 100% reporting of complications. This required blanket advertising and regular follow-up.

The process for reporting events was confidential and secure. The RCoA was fortunate that Dr David Counsell in Wrexham was establishing the National Confidential Acute Pain Critical Incidents Audit (NCAPCIA) at the same time the RCoA planned this audit. The NCAPCIA website (www.ncapcia.org.uk) acted as a clearing-house for all reports to the RCoA audit.

An example explains the reporting process. A neurologist seeing a patient with a spinal injury after an epidural reported to the project team by E mail without sending patient-specific data. The required data was the neurologist's contact details, their hospital and the hospital where the epidural took place. The NAP3 team then contacted the local reporter for the hospital where the epidural was performed and alerted them of the event. The local reporter submitted a detailed report to the NPAPCIA website where the data was validated, anonymised (if necessary) and duplications eliminated. Importantly the RCoA had no ability to (or interest in) determine which hospital or anaesthetist generated each report. The process worked identically if the patient presented to an anaesthetist, pain clinician or intensivist.

Summaries of reports were reviewed by a small review group (representing all stakeholders). The main aim of the review process being to determine a) whether the report fulfilled inclusion criteria for incidence calculation b) the extent of the injury to the patient c) causality, where possible d) learning points.

Cases meeting audit inclusion criteria were considered for use in calculating incidences (of permanent harm, of paraplegia and of death). All cases, whether meeting audit inclusion criteria or not were reviewed for learning points.

The College report was published on 12th January 2009 and the British Journal of Anaesthesia published a paper (electronically) documenting the quantitative aspects of the paper on the same day. This paper appeared in the February edition of the BJA. E-letters and letters followed in the June and July editions of the British Journal of Anaesthesia.

Results

Phase 1

The results of the snapshot survey are published [8]. Since then then 3% of unreturned reports have been acquired. The snapshot has to be regarded as a success: with a 100% return rate.

All local reporters returned data. Hospital size varied from 16-1500: median 500. Overall 92% of returned were classified as accurate by the reporters (obstetrics 94%, adult peri-operative 83%, chronic pain 94%, paediatric peri-operative 95% and non-anaesthetists 91%) with the remainder being close estimates or estimates. Most other reports were 'close estimates'. In the 2 week snapshot 28,287 central blocks were recorded. The breakdown was spinals (46%) epidurals (41%), CSE (6%) and caudals (7%). The vast majority (98.3%) were performed by anaesthetists. Specialties were obstetrics (45%), adult peri-operative (44%) chronic pain (6%) peri-operative paediatric (3%). Non-anaesthetists (orthopaedic surgeons, rheumatologists, spinal surgeons, neurosurgeons and one radiologist, one neurologist and one general practitioner) performed (1.7%) of the blocks (365 caudals, 99 epidurals, 31 spinals and 0 CSEs) in 71 hospitals.

The figures were multiplied by 25 (based on annualised data for one hospital) to provide an annual estimate of activity: see table. This suggests that slightly more than 707,000 procedures are performed annually in the UK NHS hospitals (325,000 spinals, 293,000 epidurals, 42,000 CSEs and 47,000 caudals).

SNAPSHOT						
n=	Peri-operative	Chronic	Obstetrics	Paediatrics	Non-anaesthetists	SUM

Epidural	97925	27975	161550	3125	2475	293050
Spinal	189000	1325	133525	325	775	324950
CSE	16525	0	25350	0	0	41875
Caudal	9000	11375	0	18050	9125	47550
SUM	312450	40675	320425	21500	12375	707425

Phase 2

There were 108 reports reported to the RCoA. Approximately 1 in 10 were reported by neurologists with the majority of the others reported by anaesthetists. Twenty four reports were filtered out as not severe enough to be considered by the review panel (superficial infection, post dural puncture headache) and in all other cases the LR was contacted to report the case to NCAPCIA. The following tables summarise the reports.

Clinical uncertainty in the reports and their interpretation meant that all results are presented both with an optimistic and pessimistic interpretation. Confidence intervals for all reported incidences should be reported to account for *statistical uncertainty* in the reports.

Eight four cases were reviewed by the panel. There were 30 cases of permanent harm classified pessimistically and 14 classified optimistically. There were 13 cases of permanent paraplegia/death classified pessimistically and 5 classified optimistically. There were 6 deaths classified pessimistically and 3 classified optimistically. Incidences as point estimates are appended at the end of this summary. Confidence intervals are important and are available on the College website and in the original report.

The incidence of complications is lower than many would have anticipated and is reassuring for patients and clinicians.

NUMERATOR for all permanent injuries

PESSIMISTIC

n=	Peri-operative	Chronic	Obstetric	Paediatric	Non-anaesthetist	Sum
Epidural	17	0	1	0	0	18
Spinal	5	0	2	0	0	7
CSE	3	0	1	0	0	4
Caudal	0	1	0	0	0	1
Sum	25	1	4	0	0	30

OPTIMISTIC

n=	Peri-operative	Chronic	Obstetric	Paediatric	Non-anaesthetist	Sum
Epidural	8	0	1	0	0	9
Spinal	3	0	0	0	0	3

CSE	2	0	0	0	0	2
Caudal	0	0	0	0	0	0
Sum	13	0	1	0	0	14

NUMERATOR for paraplegia/death

PESSIMISTIC

n=	Peri-operative	Chronic	Obstetric	Paediatric	Non-anaesthetist	Sum
Epidural	6	0	0	0	0	6
Spinal	4	0	0	0	0	4
CSE	2	0	0	0	0	2
Caudal	0	1	0	0	0	1
Sum	12	1	0	0	0	13

OPTIMISTIC

n=	Peri-operative	Chronic	Obstetric	Paediatric	Non-anaesthetist	Sum
Epidural	1	0	0	0	0	1
Spinal	2	0	0	0	0	2
CSE	2	0	0	0	0	2
Caudal	0	0	0	0	0	0
Sum	5	0	0	0	0	5

Most complications that were initially severe recovered within 6 months. Overall more than 60% of patients with an initial neurological deficit made a full recovery. The poorest prognosis was notably after spinal cord ischaemia and vertebral canal haematoma and to a lesser extent after vertebral canal abscess. Better outcome occurred after meningitis and traumatic nerve or spinal cord injury. The blocks most frequently associated with complications were those performed for peri-operative/acute pain indications, with the incidences of complications after obstetric, chronic pain and paediatric indications all being notably low.

Epidurals and CSEs were more frequently associated with complications than spinals and caudals.

Comparison between groups is particularly dangerous: such comparisons need to take account of differences in patients, the potential benefits of a technique and benefits and risks of avoidance of a technique and of its alternatives.

Litigation and complaints after complications were infrequent. Good practice was far more frequent than remediable care but there was some evidence of failure to monitor patients, failure to understand or act on abnormalities in a timely fashion (particularly in the post-operative setting) and failure to observe previously made recommendations. *There was therefore evidence of both unavoidable and avoidable injury after CNB.*

More clinical detail will be discussed at the meeting including discussion of individual complications, different types of block and for different indications and the resultant learning points.

Limitations.

NAP3 has limitations.

- 1 We do not know what happens in the independent sector.
- 2 We do not know what has not been reported. Under-reporting would mean the estimate is an underestimate of the incidence of complications. However underreporting of the denominator, and recovery of any cases beyond 6 months, would mean the estimate is an over-estimate.
- 3 As these events are rare, we may have been lucky, and sampled an unrepresentatively good year.

These limitations are largely unanswerable. In order to validate our data we sought numbers of cases reported to the national reporting and learning service (NRLS) to the NHS Litigation authority (NHSLA) and to the defence organisations. However these sources had not received reports that we were unaware of and also of note did not include the reports notified to us. We have also not heard of additional cases 'on the grapevine' or at meetings or in the published literature (and we have looked!)

- 4 We have only sought very serious and life-changing events.

This is indeed so, but that was our intent from the outset. A different methodology is appropriate for detecting the more frequent, but less serious, complications that may occur. It is however, probably the major complications that are traditionally least clearly defined and most difficult to discuss with patients (or colleagues) with confidence.

- 5 Finally the project only focuses on the complications of CNB.

None of the evidence-based benefits of CNB are considered. These are considered in the book *Acute Pain Management* [9] and include optimal analgesia, reduced respiratory complications after major surgery, reduced pulmonary infections and less hypoxia compared to parenteral opioids, reduced incidence of myocardial infarction and improved recovery of bowel function (with thoracic epidural analgesia) and reduced stress response to surgery. A chapter in the full report also addresses this subject.

Any consideration of the complications associated with CNB should be balanced by three further considerations 1) the benefits: proven and potential of the technique 2) the known and potential complications (and benefits) of both the analgesic alternatives such as parenteral opioids and NSAIDs and the 3) consequences of less good analgesia. At present the debate often neglects these considerations.

Response and feedback to NAP3

There was widespread international media interest in the results on NAP3. This focussed almost exclusively on epidurals in labour and obstetrics. In contrast all correspondence to the academic literature, to date, has emphasised the relatively higher incidence of complications in the peri-operative epidural group and some suggest the report under-estimates the risks. The higher incidence of complications in the peri-operative group is certainly apparent but so is the difference in the patients, their potential benefits from CNB, their potential risk from other analgesic modalities and from poor analgesia. Careful analysis suggests that comparisons with Moen and other's reports are unsuitable: as an example while Moen reported almost 40% of complications were caused by meningitis or cauda equina syndrome: these same complications represent close to 7% in NAP3. For more in depth consideration see BJA letters [10-12]. The debate will continue to rage!

Summary

NAP3 has had wide support from the profession and could not have succeeded without that support. It is likely it has achieved its goals. At the very least it has collected a large series of major complications of CNB in the UK. This series of cases has been reviewed and learning points made. An estimate of the incidence of complications for central neuraxial blockade in the UK is now available and each subspecialty should be able to extract from the report point estimates of incidences of complications relevant to their practice: the evidence is that it will be the best estimate to date. It appears that the use of central neuraxial blockade has an acceptably low incidence of major complications and is no more dangerous than previous good quality reports have suggested.

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NAP 3: Point estimates of incidence (95% confidence intervals NOT stated)

Cases with Permanent Harm with CNB

Indications	Pessimistic	Optimistic
Overall	1 in 23,500	1 in 50,500
Paraplegia and death	1 in 54,500	1 in 141,500
Overall death	< 1 in 100,000	< 1 in 200,000
Peri-operative overall	1 in 12,500	1 in 24,000
Obstetric	1 in 80,000	1 in 320,000
Chronic Pain	1 in 40,000	Had full recovery
Paediatrics	No permanent Harm	No permanent harm

NAP 3: Cases with Permanent Harm with Peri-operative Epidural:

	Pessimistic	Optimistic
Overall	1 in 5,800	1 in 12,000
Paraplegia & death	1 in 16,000	1 in 98,000

NAP 3: Cases with Permanent Harm with Peri-operative Spinal:

Overall	1 in 38,000	1 in 63,000
Paraplegia & death	1 in 47,000	1 in 95,000

NAP 3: Cases with Permanent Harm with Peri-operative CSE:

Overall	1 in 5,500	1 in 8,300
Paraplegia & death	1 in 8,300	1 in 8,300