Incidence of severe complications after central neuraxial block

Editor—Cook and colleagues'1 important prospective audit confirms that epidural procedures are associated with permanent harm much more frequently in the general perioperative population than in the obstetric setting and that spinal anaesthesia is relatively safe. An individualized approach to the informed consent process is emphasized in the accompanying editorial,2 where the risk discussed with a particular patient is tailored to the clinical indication instead of providing the overall headline figure.

It can be argued that the 22 patients who made a complete recovery (and the other cases with full recovery before notification) should have been included in the analysis because these complications had the potential to cause a permanent motor deficit or death. Undoubtedly, the clinicians involved (and the patients themselves) would categorize these serious complications as ‘major’ in view of the complex multidisciplinary care often required to avoid a poor outcome and, as such, these cases are relevant when discussing material risk with a patient. Using data from the full NAP3 report,3 the risk of a severe neurological complication after perioperative epidural anaesthesia is calculated to be 1:3703 (n=100000) when the patients who recovered are included. This is strikingly similar to the figure of 1:3888 (n=245000) derived using similar definitions from the very large retrospective study of Moen and colleagues.4

Ideally, the type of surgery would have been recorded during the snapshot derivation of the denominator,5 allowing a subgroup analysis for each surgical speciality. This sort of information is very useful clinically when deciding which anaesthetic technique to recommend to a particular patient. For example, it is thought that the presence of multiple ‘red flags’ such as degenerative spine and concurrent anticoagulant treatment among patients undergoing total joint replacement greatly increases the risk of a serious complication after epidural block.4 6

However, with 100% participation from NHS hospitals, the project has achieved its aim of providing good quality, up-to-date data for clinicians, and the authors are to be congratulated.

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Editor—We thank Dr Fowler for his interest in and compliments about the Third National Audit Project of the Royal College of Anaesthetists (NAP3).1 His letter raises several points which we will respond to in order.

First, we would endorse his inference that informed consent requires accurate and specific information about risk. It was the primary aim of NAP3 to generate this information for central neuraxial block (CNB). NAP3 generated both optimistic and pessimistic estimates of the incidence of permanent harm after CNB ‘overall’ and for each of four types of CNB with four broad clinical indications. This generates >30 incidences of harm for specific block types and specific indications, each with relevant 95% confidence intervals. For many anaesthetists, this provides enough (and for some too many) figures to quote to patients during the consent process.

We would respectfully disagree that the patients with fully recovered complications should be included in calculations of incidence because ‘these complications had the potential to cause a permanent motor deficit or death’. Taken to its logical conclusion, Fowler would have us include all patients receiving CNB because all may ‘potentially be harmed’. The patients who were excluded from analyses were those who made a full and documented recovery within 6 months. As our endpoint was permanent harm (conservatively defined as persisting deficit 6 months after CNB), it would be quite wrong to include those patients who clearly did not meet this definition. Had we chosen an endpoint such as ‘material risk’ or ‘major harm’, a minority of these cases may indeed have been included, but we did not: in part, because of the impracticality of defining and determining such endpoints with clarity. We consider it an important learning point from the project that >60% of those patients with initially important neurological complications made a full documented recovery within 6 months. As Buggy’s2 editorial points out, our pessimistic incidences may indeed overestimate the risk because we included some patients either lost to follow-up (where recovery may well have occurred) and some where causation was not proven. Of note, our quoted incidence of laminectomy does include some of the patients referred to by Dr Fowler, who were initially harmed but made a subsequent full recovery.

Dr Fowler states that the incidence of severe neurological complications after perioperative epidural in NAP3 is 1 in 3703 and comments that these results are similar to those of Moen and colleagues.3 For a number of reasons we advise against this calculation and comparison. First, it is not clear how he derives this figure. Second, due to the type of cases we sought to be reported and the...
methodology we used to exclude cases of full recovery we may have missed cases that Moen would have included. Third, the distribution of complications differs markedly between the two studies. As an example, in Moen and colleagues’ paper almost 40% of complications were caused by meningitis or cauda equina syndrome; these same complications represent close to 7% of those reported to NAP3. Whether such differences are historical or geographical is likely to be impossible to determine but it suggests the population of injuries we studied was quite dissimilar. Finally, assuming Fowler’s figure is based on the 28 neurological complications that occurred after perioperative epidurals and CSEs: of these, five had almost complete or complete resolution of symptoms even at the time of notification so were, at worst, transient. Ten (including these five) made a documented full recovery within six months and, of the 28, only eight were included in the optimistic interpretation of the data. We therefore intentionally did not analyse our results on this basis and we discourage Fowler’s analysis of our data because we believe that it is not based on robust data capture or case analysis.

Dr Fowler suggests that the project might (ideally) have been used to determine the risk of CNB for each surgical specialty (and by extrapolation perhaps for each operation). This would have required collection of data such as the indication for every CNB performed in the UK for a whole year. This is also true regarding resolving interesting questions such as whether CNB performed awake or anaesthetized is associated with more harm. We spent a considerable time deciding how much information to request from our colleagues in the census stage of the project, because it is only by determining denominator data that one can then calculate an incidence. We eventually decided that there was more to be gained by return of a limited amount of data from all hospitals, than extensive details from only a few. We believe we were vindicated in this decision by a 100% return rate in the census stage, but this figure should not hide the enormous amount of effort required to achieve such a return. We have no doubt at all that had we attempted to gain considerably more information at the census stage of the project, returns would have been low, and the project would have failed.

Finally, Dr Fowler refers to work relating to lower limb arthroplasty and raises the possibility that total joint replacement and epidural anaesthesia are a particularly hazardous combination. Moen and colleagues’ data have also been reported in support of this contention. We discuss in some detail in our report why such subgroup analyses are potentially misleading, particularly when numerators and denominators are small, with the consequence of increasingly wide confidence intervals around any point estimate of risk. Regarding joint arthroplasty, in the period during which NAP3 ran, more than 100 000 lower limb arthroplasties were performed in the NHS in England and Wales (personal communication Mr I. Mulcahy, National Joint Registry). As NAP3’s denominator also included Scotland and Northern Ireland, the denominator will considerably exceed 100 000 operations. Although the NJR data do not allow us to state, with confidence, how many of these operations were performed under CNB, nor how many under epidural, we can state that only one of the 50 adult perioperative non-obstetric cases reviewed by NAP3 (including those later excluded on the grounds of date of CNB or hospital funding) was a lower limb arthroplasty, in which epidural anaesthesia was the CNB. Of these 50 cases, 13 underwent orthopaedic surgery including eight primary joint replacements and two revision joint replacements. Six spinalis and two combined spinal–epidurals (CSEs) were used for primary arthroplasty and one CSE and one epidural for the revision arthroplasties. Permanent harm (pessimistically interpreted) occurred after two spinalis, three CSEs, and one epidural. Without robust denominators, interpretation of these data is difficult, but we can be reassured that we did not uncover an epidemic of epidural-related harm after orthopaedic arthroplasty.

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5 Cook TM, Mihai R, Wildsmith JAW. A national census of central neuraxial block in the UK: results of the snapshot phase of the Third National Audit Project of the Royal College of Anaesthetists. Anaesthesia 2008; 63: 143–6

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Clinical outcome benefits of pretreatment with levosimendan

Editor—Recently, Tritapepe and colleagues1 reported that pretreatment with levosimendan in patients undergoing elective surgical myocardial revascularization results in