Major complications of central neuraxial block: the Third National Audit Project: some comments and questions

Editor—The Third National Audit Project (NAP3) is the largest prospective study regarding the incidence of complications after central neuraxial blocks (CNBs) performed. All collaborators are to be congratulated with the success of this ambitious project. The numbers of patients and complications included are considerable, and highly reliable information was obtained.

Unfortunately, the impact of the results might be reduced by their presentation. Obstetric patients, well known to constitute a low-risk group, are included in the denominator, predictably reducing the incidence of complications. In accordance with the endpoints of the study (permanent damage or death), successfully treated complications are excluded from statistics presented in the abstract (and press release), also contributing to a lower incidence of complications. However, patient outcome is dependent on vigilance and suspicion of a complication, in turn largely based on the perceived probability of such a complication arising. The present study illustrates this relationship, as permanent damage in many cases might have been avoided by more timely action. Subgroup analysis of patient groups at higher risk for complications is therefore of great value.

The next step, risk–benefit analysis, has recently been performed in well-defined patient categories. Some studies show questionable benefits of perioperative epidural blockade (EB), as in cardiac patients and after liver resection, in spite of the fact that in these patient groups, the acceptable risk level is much higher than the risk level acceptable to the obstetric patient requiring pain relief during labour. This difference is another argument in favour of separating obstetric CNBs from all remaining CNBs.

The distinction of outcomes as ‘optimistic’ or ‘pessimistic’ introduces a new dimension of difficulty in the preoperative colloquium. The prospect of an operation without neurological damage ‘following uneventful CNB’ when compared with ‘following complicated CNB but with successful laminectomy’ to most patients probably sounds like two altogether different stories, leaving the patient with an impossible choice.

During the 1990s, it was believed that the higher incidence of vertebral canal haematoma (VCH) in the USA was caused by thromboprophylaxis with higher dosage of low-molecular-weight heparin compared with European countries. The lower incidences in Europe were calculated from case reports in the literature and assumed numbers of blocks. The high incidence of VCH in the USA was confirmed in our study in Sweden. Recalculating our results for comparison with NAP3, the incidence of VCH after non-obstetric perioperative EB was 1:10 200, compared with the incidence of 1:19 500 in the NAP3. Female orthopaedic patients constituted a high-risk group in the USA and in Sweden, in our study with an incidence of VCH as high as 1:3800. The NAP3 does not define numbers of orthopaedic EB, and it is unclear whether the use of orthopaedic EB has diminished in the UK, as it undoubtedly has in Sweden, after the results of these studies.

The discrepancy of complications in obstetric vs orthopaedic patients is important not only for the application of CNB in everyday clinical practice, but also for the understanding of the pathophysiology of the complications. Specific pathology and non-specific age-related processes cause narrowing and closing of the vertebral canal. Consequently, in the case of VCH in an elderly patient, the volumes causing symptomatic compression may be inferior to those injected performing a blood patch for treatment of post-dural puncture headache in the obstetric patient. Magnetic resonance images show an epidural blood patch leaking through the intravertebral foramina of young individuals, but in an elderly lady with spinal pathology images show compression of the medulla caused by local anaesthetic (and cerebrospinal fluid). This could have been the pathophysiology behind some of the cases presented in the NAP3.

According to the press release covering NAP3, overall incidence of complications was much lower than previously believed. This good news would have been plausible, considering the possible impact of several studies published in recent years. And indeed, compared with the overall incidences of ~1:1000 after perioperative EB reported by two recent reports, the incidences in the NAP3 are lower, even including completely resolved cases.

However, the overall incidence of complications after perioperative EB in NAP3 was almost identical to the incidence found in our study. In NAP3, 26 complications associated with 97 925 perioperative EB (excluding one cardiovascular collapse) and two complications after 16 525 combined spinal–epidural (CSE) allow an incidence of 1:4000. In Sweden, 63 complications in 245 000 perioperative EB (including CSE) account for an incidence of 1:3880.

For the individual patient, there is little, if any, difference in probability of developing a complication according to any one of these above-mentioned incidences. But do
the results of the NAP3 study really support the conclusion that the risks are much lower than perceived? In addition, the verbal description of incidences probably influences future anaesthesiologic practice more than naked numbers. Overoptimistic interpretation of data might therefore retaliate, and that would be a sad way to dissipate the results of this extensive and successful work.

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Editor—We welcome Dr Moen and colleagues’ interest in the Third National Audit Project of the Royal College of Anaesthetists (NAP3).1 It is particularly welcome because they are the authors of a widely quoted study on the same topic.5 Their letter is long and there is not enough space to address each issue raised in full here. In addition, much of what we might say was published in the full project report to which we would refer them and other readers.12 We believe that this is appropriate; the article published in the British Journal of Anaesthesia stands on its own, but it is primarily a quantitative analysis and précis of a very large audit, and the report (freely available on the website of the Royal College of Anaesthetists)12 is a more discursive document.

Before addressing their letter in detail, it is perhaps worth commenting that, although the project results received a lot of media interest and considerable international coverage, not a single enquiry from a journalist was related to perioperative CNB. Indeed, our efforts to publicize those results (which were included in all press releases) were repeatedly thwarted by journalists, who reported exclusively on the project’s relevance to obstetrics. In contrast, all the academic correspondence to date has focused almost entirely on perioperative CNB. This dichotomy of focus is worthy of reflection.

Dr Moen and colleagues raise numerous points, but we will respond only to those relating specifically to the NAP3 results. They emphasize the difference in the risk of complications associated with obstetric and perioperative CNB. We quite agree, and that is why all NAP3 results are presented by clinical indication. Further, in the full report,12 the complications relating to each clinical indication are discussed in a dedicated chapter, each of which presents the quantitative data for CNB performed for that indication. Differences in outcome according to clinical indication are emphasized in the executive summary of the report and elsewhere. Finally in Appendix 4 of the report, the full results (by indication and type of CNB) are reported. Of note, we also emphasize widely the pitfalls of comparing incidences between such groups without considering case mix and other factors which make such groups dissimilar.

Like Fowler,13 Moen and colleagues suggest that NAP3 underestimates the incidence of complications because only complications leading to permanent harm (defined as death or persisting deficit at 6 months after CNB) were included. We agree that there will have been lesser complications of CNB that were not notified to NAP3 and we also excluded serious complications from which patients made a full and documented recovery within 6 months. In order to generate meaningful data from a review of remote reports, it was important that NAP3 used a readily defined and clinically meaningful outcome measure. NAP3 therefore did not include neuropraxias (or other injuries) resolving at 6 weeks or 3 months, or indeed 6 months, but only those leading to persisting deficit at 6 months. NAP3 used a 6 month ‘cut-off’ and included all persisting deficits, a definition of harm which was considered to be clinically relevant to patients and anaesthetists. We accept that not everyone will agree with this judgement. In contrast to Moen and colleagues, Buggy’s14 accompanying editorial suggested that as some injuries may resolve beyond 6 months, NAP3 may have overstated the incidence of complications. NAP3 did not seek lesser or shorter lived complications and we have no idea how many such complications occurred in our cohort. We therefore intentionally did not analyse our results on this basis and we discourage Moen and colleagues’ analysis of our data because we believe that it is not based on robust data capture or case analysis. For instance, five of the 28 cases they refer to had almost complete or complete resolution of symptoms even at the time of notification so were, at worst, transient. Further, 10 (including these five) made a documented full recovery within 6 months, and of the 28, only eight were included in the optimistic interpretation of the data.

Moen and colleagues also take issue with the use of pessimistic and optimistic interpretations of events reviewed by NAP3. This is discussed both in the paper and the full report of the project and all review panel members were in agreement with the decision to report the data in this manner. All also agreed that the pessimistic interpretation was indeed pessimistic. Of note, one of the authors considered that the term pragmatic was a more accurate description of the second group, but it was ultimately agreed to use the more cautious term optimistic. NAP3 reports all results with both pessimistic and optimistic interpretation, and each with 95% confidence intervals: addressing both clinical and statistical uncertainty. In practical terms, this provides clinicians with the opportunity to discuss the data with each patient in as much detail as is appropriate. Some may choose to present a single figure, some the range of optimistic and pessimistic point estimates. Some anaesthetists may find this confusing, but by presenting our data as fully and openly as possible we enable clinicians to understand the origin and ‘provenance’ of the data.

We leave them to decide which figures they then choose to use in their clinical practice. Whether the patient had a laminectomy or not was not a factor in classifying outcome.
Moen and colleagues compare one of the point estimates of risk in their study with one of the pessimistic point estimates of NAP3. The use of point estimates rather than confidence intervals undermines this comparison and both pessimistic and optimistic incidences should be considered. Of note, many of the groups in their report had considerably smaller denominators than those in NAP3, and the point estimates therefore have wide confidence intervals. This applies particularly to those with small numerators.\textsuperscript{15,16} As discussed in both the paper and the full report, Moen and colleagues place much emphasis on the apparently higher risk associated with female orthopaedic (specifically knee replacement) surgery. However, the apparently zero risk (from their figures) in males undergoing hip replacement and the almost 10-fold lower risk in females undergoing hip replacement are rarely commented on. In order for the comparison between the earlier figures and NAP3 to be valid, the two studies must be methodologically very similar: although NAP3 identified denominator data directly and completely, and sought to identify permanent harm associated with CNB of whatever cause, their study used more secondary calculations to determine denominators, and the complications sought were primarily only neurological and appear to have been less clearly defined. For instance, it is not clear whether cases of spinal cord ischaemia or traumatic peripheral nerve injury were included in their study and it is apparent that wrong route errors, cardiovascular collapse, and drug overdose were not.

A further reason to be cautious about comparisons between these studies is that the distribution of complications differs markedly. 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 the pages of journals and coffee rooms of anaesthetic departments. The NAP3 results should not replace previous estimates with CNB, but rather refine them. Although NAP3 does not provide a definitive calculation of risk, because of its size and completeness we believe that its estimates are at least as robust as any previously published. It is welcome when a study generates debate and we thank Drs Moen and colleagues for their contribution to this debate, which no doubt will continue within the pages of journals and coffee rooms of anaesthetic departments.

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