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How safe are regional techniques? Evidence from large studies with big data

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Introduction

The issue of the safety of regional anaesthetic techniques can only be addressed by a careful examination of the complications that may occur. These injuries can be caused by a variety of mechanisms, including sharp and blunt trauma, drug neurotoxicity (including the wrong drug), compressive injury (notably spinal haematomas), stretch injury and nerve ischaemia.[1] The nature of the regional technique is a major determinant of the risk of injury, and neuraxial techniques have been studied to a far greater extent than those involving peripheral nerve blockade. The major problem in studying the safety of regional techniques is that the standard tools of randomised controlled trials and meta-analysis are inappropriate for a proper assessment of rare events, such as neurological injury.[2] Most of the references to adverse effects, particularly those associated with peripheral procedures, are to be found as single case reports, and thus are difficult to assess using standard trial methodology.

Concerns regarding possible neurological injury following neuraxial anaesthesia have been in existence for a long time, dating back to the famous Wooley and Rowe case in the 1950s.[3] Numerous case reports were collected in one of the earliest attempts at a systematic review of the literature, but a risk rate could not be estimated as the denominator was unknown.[4] The largest single study on the risks of neuraxial blockade was published by Moen, Dahlgren and Irestedt in 2004.[5] The 127 complications found included spinal haematoma (33), cauda equina syndrome (32), meningitis (29), epidural abscess (13) and miscellaneous (20). Permanent neurological damage was observed in 85 patients. The incidence of complications after spinal blockade was within 1:20 000-30 000 in all patient groups. The incidence after obstetric epidural blockade was 1:25 000, it was 1:3 600 (p-value < 0.0001) in the remaining patients. Spinal haematoma, after obstetric epidural blockade, carried an incidence of 1:200 000, significantly lower than the incidence of 1:3 600 females subject to knee arthroplasty (p-value < 0.0001).[5] A later systematic review estimated the rate of neural injury after spinal and epidural anaesthesia to be 3.78:10 000 [95% confidence interval (CI): 1.06-13.50:10 000) and 2.19:10 000 (95% CI: 0.88-5.44:10 000)], respectively.[6]

Recognising the problems of traditional techniques, Cook et al conducted a national audit in the UK. As a result of the difficulties in determining the precise cause of neurological injury, these authors classified their results into "pessimistic" and "optimistic" groups. All reported neurological complications were allocated to the anaesthetic technique in the former, and in the latter, only those that could be clearly attributed to anaesthesia were included. A reporting rate of 92% of the hospitals surveyed was achieved, with over 700 000 regional procedures included. The incidence of permanent injury due to central neuraxial block (expressed per 100 000 cases) was "pessimistically" 4.2 (95% CI: 2.9-6.1) and "optimistically" 2.0 (1.1-3.3). "Pessimistically", there were 13 deaths or paraplegias, "optimistically" five. The incidence of paraplegia or death was "pessimistically" 1.8 per 100 000 (95% CI: 1.0-3.1) and "optimistically" 0.7 (95% CI: 0-1.6). Two thirds of initially disabling injuries resolved fully. The most common causes of injury were infection, vertebral canal haematoma and nerve injury.[2] These suggest a substantially lower risk than that previously estimated.

Closed claims analysis has also been used to estimate risks. In an early study, 670 (16% of 4 183) claims were for anaesthesia-related nerve injury. The most frequent sites of injury were the ulnar nerve (28%), brachial plexus (20%), lumbosacral nerve root (16%) and spinal cord (13%). Ulnar nerve (85%) injuries were more likely to have occurred in association with general anaesthesia, whereas spinal cord (58%) and lumbosacral nerve root (92%) injuries were more likely to occur with regional techniques. Spinal cord injuries were the leading cause of claims for nerve injury which occurred in the 1990s.[7] Following a subsequent analysis of claims in the 1990s, it was reported that 308 claims were associated with regional anaesthesia (versus 642 claims associated with general anaesthesia). The percentage of these claims for patient death (10%) showed a decline from more than 20% in the 1970s. The primary reason for death was cardiac arrest associated with neuraxial blockade, though this represented only 30% of the deaths, as opposed to 61% in the 1970s. There were 71 permanent disabling injuries among the 308 claims. The most common of these (23%) was associated with nerve blocks of the eye (13 retrobulbar and three peribulbar). Second in frequency (21%) were pain-management related claims involving neuraxial opiates or neurolytic blocks. Third (20%) were nerve injuries

associated with neuraxial and peripheral blocks, followed by epidural haematomas (13%).[8] Obstetrics had a higher proportion of neuraxial anaesthesia claims with temporary and low-severity injuries (71%), compared with the non-obstetric group (38%, p-value ≤ 0.01) and a lower proportion of claims with death or brain damage and permanent nerve injury, compared with the non-obstetric group (p-value ≤ 0.01).[9] Most peripheral nerve block claims were associated with temporary injuries. Local anaesthetic toxicity was a major cause of death or brain damage in these claims.[10] In the UK, approximately half of the claims (186/366, 51%) related to obstetric anaesthesia and analgesia, and of the non-obstetric claims, the majority (148/180, 82%) related to neuraxial block. Non-obstetric claims were more likely to relate to severe outcomes than obstetric ones. High-value claims related to neuraxial blocks and eye blocks, rather than to peripheral nerve blocks.[11] The most recent report is from Finland, and reported 216 closed claims relating to spinal or epidural blocks. Fatalities occurred in 1:775 000 cases of spinal anaesthesia for surgery, 1:62 000 cases of epidurals for surgery or acute pain relief, 1:12 000 epidurals for chronic pain relief, 1:89 000 combined spinal and epidural anaesthesia for surgery and 1:144 000 epidurals for labour. The incidence of neuraxial haematoma after spinal block was 1:775 000, that for epidural block 1:26 400, and in the case of combined spinal and epidural anaesthesia, 1:17 800. Irrespective of the method of neuraxial technique, the most serious complications were in elderly patients with co-morbidities.[12]

Overall, the risk of neural injury following a neuraxial technique appears to be somewhere in the region of 5-7/100 000 procedures. The incidence is significantly lower for peripheral blocks, but an accurate assessment of the probability of risk is very difficult as a result of the rarity of the events. Furthermore, the recovery rate for peripheral injury appears to be higher than that for neuraxial damage. Nevertheless, it can be devastating when it occurs.

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