References


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Anesthesia Safety, Outcomes, and Prospective Study Design

To the Editor.—We congratulate Auroy et al.1 for the new and valuable information resulting from their survey of regional anesthesia in France. The study provides data that confirm the safety of modern anesthesia practice. Clearly, it is rare for regional anesthetic techniques to produce serious complications. Although some excellent information is provided, we are concerned that the study results have been overinterpreted.

First, this was not truly a prospective study. Prospective data collection is achieved when “the relevant prognostic and outcome variables are collected from patients as they are treated.”2 In this study, the questionnaire used to assess total number of anesthetics and number of serious complications was “sent to all participating anesthesiologists 15 days before the end of the 5-month period.”3 Although not technically prospective, this portion of the data collection could be considered prospective only if the questionnaire eliminated, rather than added, new data fields to those on the original log data sheet. We accept that it is unlikely that anesthesiologists would forget to report serious complications that occurred in the previous 5 months and that these data are likely to be accurate.

In contrast, data regarding potential risk factors for serious complications clearly were not collected prospectively. Data collection forms for potential risk factors (e.g., local anesthetic choice; sensation of paresthesia during needle insertion, use of continuous microcatheters) were designed and mailed to investigators 1 month after the study was completed. Furthermore, because accuracy of these data were not verified by retrospective review of patient records, the possibility of incomplete and biased data reporting cannot be excluded.

Indeed, the data suggest a recall bias in reporting for patients with neurologic deficits. Of the 14 patients in whom a neurologic deficit developed after bupivacaine spinal anesthesia, 11 anesthesiologists remembered the occurrence of a paresthesia during placement of the spinal needle (table 1). In contrast, of the 10 patients in whom neurologic injury developed after lidocaine spinal anesthesia, only one anesthesiologist remembered the occurrence of a paresthesia during placement of the spinal needle. Because these data were not collected prospectively, it would seem prudent, at least, to retrospectively review anesthetic records to verify the accuracy of these recollections.

Even if it is assumed that the recollections are accurate, one must ask, are these data sufficient to support speculation regarding risk for nerve injury? We think the answer is no, for several reasons. First, the denominator was not measured. By design, detailed data were only collected for patients experiencing a complication. For example, anesthesiologists were asked to recall choice of local anesthetic for only 97 of 105,730 regional anesthetic procedures included in this study. As a result, it is impossible to calculate the true incidence of injury associated with any specific factor, including choice of local anesthetic. It is also impossible to determine whether the incidence of nerve injury differs based on choice of local anesthetic.

Second, even if incidences were identified accurately, univariate data analysis is not sufficiently robust to support speculation regarding potential cause-effect relationships. For example, it is certainly possible that lidocaine was chosen more frequently in a patient population with an inherently high risk for nerve injury (e.g., patients placed in the lithotomy position). In this scenario, lidocaine would be used more frequently in patients in whom nerve deficits developed, and univariate statistical analysis may incorrectly identify lidocaine as a risk factor for nerve injury. Because data regarding other potential risk factors were not collected, it is impossible to conclude whether any single factor, such as lidocaine use, is associated with an increased risk for serious complications.

Finally, assumptions made in the post hoc data analysis clearly bias interpretation of the results. For example, it was assumed that a transient paresthesia occurring during insertion of the spinal needle was the cause of subsequent neurologic deficit. However, transient paresthesias frequently are elicited during placement of spinal needles, and there are no data to prove this causes postoperative neurologic deficit. The decision to exclude patients with transient paresthesias during needle insertion skews the analysis (11 of 12 patients excluded because of paresthesia received bupivacaine). When all cases of neurologic deficit are included in the analysis (table 1), 10 patients (42%)

| Table 1. Characteristics of Patients with Neurologic Deficit after Spinal Anesthesia |
|-----------------|-----------------|-----------------|
|                  | Lidocaine 5%    | Bupivacaine 0.5% | Total |
| Paresthesias or pain | 1               | 11              | 12    |
| No paresthesias or pain | 9               | 3               | 12    |
| Total             | 10              | 14              | 24    |

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received hyperbaric lidocaine, 5%, and 14 (58%) received hyperbaric bupivacaine, 0.5%.

The authors conclude that intrathecal administration of lidocaine to patients who do not describe pain or paresthesias during needle placement is associated with 75% of the neurologic injuries in that group. If one agrees with this conclusion, then logically one must also agree that administration of bupivacaine is associated with 92% of all neurologic injuries in patients who have pain or paresthesia during needle insertion. In addition to the authors conclusions, these data suggest that lidocaine may be neuroprotective in patients who have paresthesia during needle insertion. Clearly, each of these conclusions is based on flawed assumptions and post hoc evaluation of an incomplete database.

In conclusion, we applaud the authors for the insights their study provides into the relative risk of serious complications associated with different techniques of regional anesthesia. However, the study was not designed prospectively to collect sufficient data to define risk factors for serious complications. In the absence of such data, specula-

lation that any single factor increases the risk for serious complications is not justified scientifically.

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References
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In Reply—The most important part of the letter by Drs. Price and Carpenter begins shortly before the paragraph that introduces their table 1. Before that, the letter reviews the caveats presented in the original article, or in the two editorials that accompanied it. These clearly stated and discussed interpretative limitations imposed by not knowing how many spinals were performed using lidocaine or how many were performed using bupivacaine. With respect to whether the study was prospective, we also note the “ideal” concern of R. L. Smith’s editorial (1990) that data for the “relevant prognostic and outcome variables are collected from patients as they are treated.”

Such was attempted in the study design, with the primary data being recorded as the patient was treated and the questionnaires being used to gather such data from those who treated the patients. As explained in the original article, all participants knew they were participating before the study took place, before regional anesthesia was administered, and before data were entered in the anesthetic record or on the questionnaires. Also, all physicians knew there would be follow-up inquiries about the cases. The questionnaire procedure was very different from a retrospective approach, in which unexpected inquiries are made to surprised individuals, asking them whether they recall various procedural events. Coincidentally, the thoughts cited by Drs. Price and Carpenter (1990) are addressed in a more recent editorial (1998) by Dr. P. G. Duncan 2 entitled, in part, “That was then, this is now!,” in which practical limitations to large observational studies are acknowledged. Such limitations include logistics and cost, and the Duncan’s 2 editorial offers the possibility that, in the 21st century, some readers will be able to find at least one technical flaw in every future trial or study conducted. The crucial issue, however, as stated by Duncan, 2 is, “when do data from an observational study achieve the standard necessary to become incorporated into one’s evidence-based medical practice?”

Drs. Price and Carpenter state that our data “suggest a recall bias in reporting for patients with neurological deficits.” They then construct their table 1 to argue this point. We are concerned that their table reflects a superficial assessment. If paresthesia or pain were totally independent of the agent used, (i.e., as in paresthesia or pain during needle insertion only), then statistically equal divisions of “paresthesia or pain” and “no paresthesia or pain” might be expected in the lidocaine and bupivacaine groups of their table 1. Because one starts with the group that had deficits, there is no a priori reason why the incidence of paresthesias and pain must be the same in both drug groups. The text of our article clearly refers to pain during injection, which might be agent dependent. It is possible that “no pain” during injection occurs less frequently during injections of a particular toxic substance than during injection of another less-toxic substance. Thus, the numbers in their table 1 do not form the basis for their subsequent reasoning that we have proven an obviously absurd hypotheses (i.e., that paresthesia and pain during needle insertion before bupivacaine injection is more likely than paresthesia and pain during needle insertion before to lidocaine injection or that pain during lidocaine use is neuroprotective). In the next to last paragraph of their article, Drs. Price and Carpenter need to change “paresthesia during needle inser-

Table 1. Characteristics of Patients with Permanent Neurologic Deficit after Spinal Anesthesia

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<tr>
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<th>Lidocaine 5%</th>
<th>Bupivacaine 0.5%</th>
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