

Major Complications of Regional Anesthesia in France

The SOS Regional Anesthesia Hotline Service

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Background: Several previous surveys have estimated the rate of major complications that occur after regional anesthesia. However, because of the increase in the use of regional anesthesia in recent years and because of the introduction of new techniques, reappraisal of the incidence and the characteristics of major complications is useful.

Methods: All French anesthesiologists were invited to participate in this 10-month prospective survey based on (1) voluntary reporting of major complications related to regional anesthesia occurring during the study period using a telephone hotline service available 24 h a day and managed by three experts, and (2) voluntary reporting of the number and type of regional anesthesia procedures performed using pocket booklets. The service was free of charge for participants.

Results: The participants (n = 487) reported 56 major complications in 158,083 regional anesthesia procedures performed (3.5/10,000). Four deaths were reported. Cardiac arrest occurred after spinal anesthesia (n = 10; 2.7/10,000) and posterior lumbar plexus block (n = 1; 80/10,000). Systemic local anesthetic toxicity consisted of seizures only, without cardiac toxicity. Lidocaine spinal anesthesia was associated with more neurologic complications than bupivacaine spinal anesthesia (14.4/10,000 vs. 2.2/10,000). Most neurologic complications were transient. Among 12 that occurred after peripheral nerve blocks, 9 occurred in patients in whom a nerve stimulator had been used.

Conclusion: This prospective survey based on a free hotline permanent telephone service allowed us to estimate the incidence of major complications related to regional anesthesia and to provide a detailed analysis of these complications.

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IN France, the number of regional anesthetic procedures has increased 12-fold between 1980 and 1996.¹ This tremendous increase can be linked to the perception that regional anesthesia is associated with numerous advantages and with very few severe complications.² This increase has been seen not only in obstetrics but also for other surgical procedures. Numerous new techniques have been described during these two decades, and their use also explains the large development of regional anesthesia. Because major complications related to traditional techniques are rare, their exact incidence is known only approximately.³ A previous prospective survey assessed the complication rate of 103,730 regional anesthetics and was based on the voluntary participation of 736 anesthesiologists.³ However, in this study, complications were reported in detail on a written form, and the detailed numbers of each type of block performed were not recorded. Moreover, the incidence of major complications associated with the more recently introduced techniques could not be assessed at that time. Thus, we created a hotline service (SOS Regional Anesthesia Service) that had three main goals: (1) to provide online clinical help for the practitioner facing a severe complication, (2) to obtain immediately relevant clinical information for every complication reported, and (3) to estimate the incidence of complications from a prospective declaration of all regional techniques performed by practitioners who had subscribed to the service.

Methods

Three weeks before the beginning of the study period, a letter was mailed to 8,150 French anesthesiologists introducing the concept of the hotline service and inviting them to participate in a survey of complications of regional anesthesia from August 1, 1998, to May 31, 1999. The service was free of charge. A 2-month period (June and July 1998) was used as a test period, and data collected during this initial phase were not entered into the database. The survey was divided into five periods of 2 months each. The participants were informed of the cellular phone number where they could reach one of three experts (D.B., C.E., K.S.) 24 h a day and 7 days a week for any question related to regional anesthesia (complication or advice). The participants were asked to report immediately any serious adverse event they encountered after regional anesthesia by calling the hotline. Nine severe complications were tallied: (1) cardiac

arrest requiring cardiac massage and/or epinephrine; (2) acute respiratory failure requiring tracheal intubation and/or assisted ventilation; (3) seizures; (4) peripheral nerve injury, defined as a sensory and/or motor deficit with clinical and/or electrophysiologic abnormalities suggesting a peripheral site of injury and no evidence of spinal cord lesion; (5) cauda equina syndrome; (6) paraplegia; (7) cerebral complication; (8) meningeal syndrome; and (9) death. The complications described during each telephone call were recorded using a preprinted form. Postdeclaration follow-up of each case was performed by the expert who received the initial call.

Each expert remained "on call" during a 1-week period, at the end of which the cases were sent by electronic mail to the other experts for reading. During the week on call, each expert was autonomous for the responses given. However, because a given individual's expertise cannot be complete for every topic, the experts could communicate within the group to discuss difficult questions, ask for advice from experts outside of the group, or even delay nonurgent responses to improve their own knowledge by reading pertinent literature or consulting medical databases.

The events reported were later reviewed by the three experts to decide whether they should be included in the "serious complications" list. Then, serious complications were classified into three groups: (1) unrelated to regional anesthesia and entirely explained by nonanesthetic factors, (2) related to regional anesthesia, and (3) unclassified. Causal inference was decided by consensus among the experts and was based on the following factors: complication temporally related to regional anesthesia occurring in an anatomic area corresponding to the lesion (except for systemic complications) and no other obvious cause found. Three other experts (F. Bonnet, M.D., J. Hamza, M.D., and L-J Dupré, M.D., listed in the Acknowledgments) not involved in the overall process of the study were asked to provide their own conclusions on 20 randomly selected cases using the same classification.

To precisely calculate the incidence of complications after each type of block, the following system was organized to record all blocks performed. A 17-page pocket booklet was prepared, in which each page was dedicated to a specific regional block. Obstetric and pediatric cases were also specifically recorded. For spinal anesthesia, the drug used (bupivacaine or lidocaine) had to be recorded. After each anesthesiologist had agreed to participate, he or she was sent a booklet covering a 2-month period. At the end of this period, the booklets were returned, and a new one was sent by regular mail. The booklets were used only to report the number of blocks performed, whereas complications were reported *via* telephone calls.

Since, in the present study, one observation corresponds to one anesthetic procedure, and because each anesthesiologist reported several procedures, the observations are not independent from a statistical point of view. This phenomenon corresponds to a "cluster effect," which leads to a bias in the calculation of the SD and the *P* value. To correct this bias, we used a bootstrap procedure⁴ designed specifically for the present study through a routine in S-PLUS 2000 (MathSoft, Seattle, WA). The exact variance of the incidence of complications was computed in this way. The naive variance was also computed, and the ratio of both variances (design effect) was systematically between 2.2 and 2.4. Thus, all confidence intervals or statistical tests were computed using naive variance increased by a factor of 2.4.

In the tables and in the text, data that approximately follow a normal distribution are presented as mean \pm SD, whereas non-normally distributed data that are widely skewed are presented as median with 25th and 75th corresponding percentiles. Pearson chi-square test was used for dichotomous categorical data. To compare continuous variables, the Student *t* test was used, except when the distribution was not normal, in which case the Mann-Whitney U test was used. Formulae based on the normal distribution were used to calculate 95% confidence intervals. When the distribution was not normal, tables of the Poisson distribution were used.

Table 1. Characteristics of Anesthesiologists Who Reported No or at Least One Complication

	Anesthesiologists Who Reported at Least One Complication (n = 67)	Anesthesiologists Who Did Not Report Any Complications (n = 420)	<i>P</i> Value
Age (yr)*	45 \pm 5 (43–50)	47 \pm 6 (39–47)	NS
Nonprivate practice (%)	57	48	NS
Previous experience performing regional anesthesia (yr)*	16 \pm 6 (11–22)	16 \pm 6 (12–20)	NS
Episodes of regional anesthesia reported per participant for the study period (n)†	314 (202–555)	254 (138–450)	NS

*Values are mean \pm SD (range). †Median values (25th and 75th percentiles).

Table 2. Complications Reported and Their Relation to Regional Anesthesia

	Related	Unrelated*	Unclassified	Total
Cardiac arrest†	11	1	0	12
Respiratory failure‡	7	2	0	9
Seizures§	8	1	0	9
Peripheral neuropathy	26	7	6	39
Cauda equina syndrome#	3	1	1	5
Central neurologic event**	0	2	0	2
Meningitis	1	0	0	1
Total	56	14	7	77
Death	4	0	0	4

*Complications not related to regional anesthesia and their cause. † Amniotic fluid embolism (n = 1). ‡ Amniotic fluid embolism (n = 2). § Epileptic fit occurring lately after regional anesthesia in a patient with known epilepsy (n = 1). || Neurologic complication related to surgery, tourniquet, or patient positioning (n = 9); neurologic abnormalities existing before the block and modified by regional anesthesia (n = 2); neurologic complications occurring in an area unrelated to regional anesthesia (n = 1); neurologic complications occurring more than 1 week after regional anesthesia (n = 1). # Neurologic abnormalities existing before the block and not modified by regional anesthesia (n = 2). ** Neurologic complications related to hypertension and occurring lately after regional anesthesia (n = 1); transurethral resection of the prostate syndrome (n = 1).

Results

During the five periods of 2 months each, 487 anesthesiologists out of 8,150 agreed to participate in the study. The participants who used the hotline service performed more blocks than the mean number of blocks performed by French anesthesiologists overall (table 1). Those who agreed to participate were allowed to subscribe at any time during the study and thus received 1–5 booklets. Overall, the participants reported performing 158,083 regional blocks, including 41,251 episodes of spinal anesthesia, 35,379 epidural blocks, 1,474 combined spinal–epidural blocks, 50,223 peripheral blocks, 4,448 episodes of intravenous regional anesthesia, 17,071 peribulbar blocks, and 8,237 other blocks. These blocks were performed for surgery in adults (74.3%), children (2.8%), or for obstetric purposes (22.9%). To ascertain that a valuable denominator had been obtained, 20 randomly chosen anesthesiologists (4.1%) who had participated in the study were asked to show

their operating room records during the study period. Fifteen of them sent copies of their operating room lists within 1 month of request, allowing comparison between the numbers of blocks reported in the booklets during the study period and hospital records. Underestimation was found to be 4% (5% for spinal anesthesia, 3% for epidural anesthesia, and 2% for peripheral nerve blocks).

Sixty-eight anesthesiologists out of 487 reported 77 serious complications as defined previously. There was no significant difference for any characteristics between those who reported at least one complication and those who did not report any (table 1). Table 2 shows that only 56 complications were classified as being related to regional anesthesia. Tables 3 and 4 show the number of blocks and the incidence of each type of complication for each type of block performed for adult nonobstetric and obstetric patients, respectively. Among the 1,474 cases of combined spinal–epidural anesthesia, the 4,448 episodes of intravenous regional anesthesia, and the 17,071 peribulbar blocks performed, no severe complications were recorded. In addition, no severe complications were reported in the 4,435 blocks performed in children. Secondary analysis of the 20 selected cases showed that the three experts not involved in the hotline service were in complete agreement with the conclusions provided by the hotline experts for 19 cases, whereas only two experts agreed on the one remaining case.

Cardiac Arrest and Acute Respiratory Failure

Bradycardia was recorded before each cardiac arrest that occurred during spinal anesthesia. The three cardiac arrests followed by death were delayed (> 40 min after spinal injection) and occurred in elderly patients (> 80 yr) who had undergone hip surgery. One case of irreversible cardiac arrest occurred during a posterior lumbar plexus block. A sensory level higher than T2 and a bilateral mydriasis were noticed immediately before the arrest.

Respiratory failure occurred during the course of central blocks (spinal or epidural anesthesia) or posterior lumbar plexus blocks; none led to death. In all complications related to posterior lumbar plexus block, a high

Table 3. Number and Incidence of Serious Events Related to Central (Neuraxial) Blocks (Excluding Obstetric Cases)

	Cardiac Arrest	Respiratory Failure	Seizures	Peripheral Neuropathy	Cauda Equina Syndrome	Central Neurologic Event	Meningitis	Death
Spinal (35,439 performed)	9 (2.5) (0.0–5.1)	2 (0.6) (0.0–2.0)	1 (0.3) (0.0–1.4)	9 (2.5) (0.0–5.1)	3 (0.8) (0.0–2.3)	0 (0.0–0.8)	1 (0.3) (0.0–1.4)	3 (0.8) (0.0–2.3)
Epidural (5,561 performed)	0 (0.0–0.5)	0 (0.0–0.5)	1 (1.8) (0.0–9.0)	0 (0.0–0.5)	0 (0.0–0.5)	0 (0.0–0.5)	1 (1.8) (0.0–9.0)	0 (0.0–0.5)

Values are expressed as n (n/10,000) (95% CI).

Table 4. Number and Incidence of Serious Events Related to Upper Limb Blocks (Excluding Obstetric Cases)

	Cardiac Arrest	Respiratory Failure	Seizures	Peripheral Neuropathy	Death
Interscalene block (3,459 performed)	0 (0.0–8.7)	0 (0.0–8.7)	0 (0.0–8.7)	1 (2.9) (0.0–14.5)	0 (0.0–8.7)
Supraclavicular block (1,899 performed)	0 (0.0–15.9)	0 (0.0–15.9)	1 (5.3) (0.0–26.3)	0 (0.0–15.9)	0 (0.0–15.9)
Axillary plexus block (11,024 performed)	0 (0.0–2.7)	0 (0.0–2.7)	1 (0.9) (0.0–4.5)	2 (1.8) (0.0–6.3)	0 (0.0–2.7)
Midhumeral block (7,402 performed)	0 (0.0–4.1)	0 (0.0–4.1)	1 (1.4) (0.0–6.8)	1 (1.4) (0.0–6.8)	0 (0.0–4.1)

Values are expressed as n (n/10,000) (95% CI).

dermatomal level and a bilateral mydriasis were observed, suggesting intrathecal cephalad spread of the local anesthetic. In one case, the occurrence of respiratory failure was facilitated by preexisting morbid obesity. Finally, in one additional case, respiratory failure occurred after an erroneous dose was used during continuous spinal anesthesia.

Seizures

Seven cases of seizures occurred after epidural (n = 1) or peripheral injection (n = 6) and were related to systemic toxicity of local anesthetics. Arrhythmias were not noted in any of the cases. In one additional case, seizures occurred during spinal anesthesia at the time of cardiac arrest.

Neurologic Complications

Most neurologic complications completely resolved within 8 postoperative days. Twelve patients had a peripheral nerve injury (n = 9) or cauda equina syndrome (n = 3) after spinal anesthesia. In nine patients, neither pain nor paresthesia had been noted during puncture. All recovered completely within 3 weeks. Of those nine patients, five had received lidocaine, whereas the three patients who had paresthesia during the puncture had

received bupivacaine. In the three patients in whom paresthesia occurred during the procedure, neurologic sequelae were still present 6 months later. Neurologic complications during spinal anesthesia occurred with a statistically different incidence regardless of whether lidocaine (5/3,459 or 14.4/10,000) or bupivacaine (7/31,980 or 2.2/10,000) had been used (*P* < 0.01).

Twelve other patients had a peripheral neuropathy after a peripheral block, and seven of them had sequelae still present after 6 months. Neurologic complications were observed in nine patients in whom a nerve stimulator had been used: two had described paresthesia during puncture, and in three cases a low intensity of stimulation (< 0.5 mA) had been used during the procedure.

Discussion

With this free-of-charge regional anesthesia service involving the voluntary participation of 487 anesthesiologists, 158,083 regional blocks were prospectively recorded in a 10-month period. The calculated incidences of severe complications related to regional block are lower than 5 in 10,000 patients in this series. This “low” incidence *a posteriori* validates the concept that a large-

Table 5. Number and Incidence of Serious Events Related to Lower Limb Blocks (Excluding Obstetric Cases)

	Cardiac Arrest	Respiratory Failure	Seizures	Peripheral Neuropathy	Death
Posterior lumbar plexus block (394 performed)	1 (25.4) (0.0–126.9)	2 (50.8) (0.0–177.7)	1 (25.4) (0.0–126.9)	0 (0.0–76.1)	1 (25.4) (0.0–126.9)
Femoral block (10,309 performed)	0 (0.0–2.9)	0 (0.0–2.9)	0 (0.0–2.9)	3 (2.9) (0.0–7.8)	0 (0.0–2.9)
Sciatic nerve block (8,507 performed)	0 (0.0–3.5)	0 (0.0–3.5)	2 (2.4) (0.0–8.2)	2 (2.4) (0.0–8.2)	0 (0.0–3.5)
Popliteal sciatic nerve block (952 performed)	0 (0.0–31.5)	0 (0.0–31.5)	0 (0.0–31.5)	3 (31.5) (0.0–84.0)	0 (0.0–31.5)

Values are expressed as n (n/10,000) (95% CI).

Table 6. Number and Incidence of Serious Events Related to Regional Anesthesia in Obstetrics

	Cardiac Arrest	Respiratory Failure	Seizures	Peripheral Neuropathy	Cauda Equina Syndrome	Central Neurologic Event	Meningitis	Death
Spinal (5,640 performed)	1 (1.8) (0.0–8.9)	0 (0.0–5.3)	0 (0.0–5.3)	2 (3.5) (0.0–12.4)	0 (0.0–5.3)	0 (0.0–5.3)	0 (0.0–5.3)	0 (0.0–5.3)
Epidural (29,732 performed)	0 (0.0–1.0)	3 (1.0) (0.0–2.7)	2 (0.7) (0.0–2.4)	0 (0.0–1.0)	0 (0.0–1.0)	0 (0.0–1.0)	0 (0.0–1.0)	0 (0.0–1.0)

Values are expressed as n (n/10,000) (95% CI).

scale study is necessary to assess this issue. The incidences observed are in the range of what has been observed in other studies,^{5–15} particularly in the recent French survey.³ However, the present study was implemented to overcome several weaknesses of the previous survey. First of all, within the past 5 yr, a significant number of new regional anesthesia techniques (posterior lumbar plexus block,^{16,17} humeral block,¹⁸ popliteal sciatic block¹⁹) have entered the clinical scene, and the incidence and severity of complications that are associated with these techniques are largely unknown. Second, in France, the overall number of regional blocks has increased 12-fold in the last 16 yr.²⁰ Third, because complications were immediately declared by using the hotline, a detailed description of clinical situations could be obtained prospectively using a systematic questionnaire. The decision to consider a causal relation with regional anesthesia was thus made easier. Moreover, follow-up could be more complete.

Compared with our previous study, another difference is noteworthy: since the experts were available 24 h a day, it can be speculated that, in several circumstances, they influenced patient care and possibly helped improve outcome. Unfortunately, because of the study design, one cannot definitively prove this hypothesis. In the previous study, we could not ascertain that all of the blocks performed were declared in the booklets (leaving some doubt regarding the absolute validity of the denominator). The audit performed retrospectively in randomly chosen participants showed a very low level of underestimation, thus validating our denominator. We also could not be sure that all complications were reported (uncertainty for the numerator). However, we believe that the current design contributed to better reporting, because the participants often expressed their interest during the study. For example, participants often called the hotline because they were worried that they would not receive their next booklet in time to start the new 2-month period. One could suspect that the rate of complications for procedures performed by nonparticipating anesthesiologists is different from what we observed in our study population consisting of anesthesiologists who volunteered to participate in an audit on complications of

regional anesthesia. It is possible that participating anesthesiologists might actually encounter fewer complications than nonparticipating anesthesiologists. The former are, indeed, more skilled and perform more blocks than the average French anesthesiologist (32.5/month *vs.* 17.3/month).^{1,20,21} Incidentally, the participating anesthesiologists were more frequently employed in public hospitals (48% *vs.* 36%), but their mean age was not different (46 yr in both groups). Also, the causal link between a complication and regional anesthesia is sometimes difficult to establish. The risk of error was limited by immediate informal discussion among experts and formal analysis of all cases every 4 months in a joint meeting of experts. Moreover, external validation was obtained by comparing our conclusions on selected cases with those provided by three other experts. However, in a limited number of cases, the causal role of regional anesthesia could still not be determined. The main reasons for failure were (1) loss of follow-up and (2) electrophysiologic studies were not performed at all, were not performed on time, or were performed with a method not precise enough to make any valid conclusion.

The incidence of regional anesthesia-induced cardiac arrest may have been lower than what we found in our previous study. However, statistical tests were not applied because the data came from two different studies performed at different times with different anesthesiologists. Interestingly, however, the clinical situations in which cardiac arrests occurred were very similar and involved—in most cases, a central block performed during hip surgery in an elderly patient. We also recorded one case of cardiac arrest and two respiratory complications (not leading to cardiac arrest) that occurred during a lumbar plexus block performed *via* the posterior approach (incidence of severe complication, 80/10,000). These three complications were related to cephalad diffusion of the local anesthetic in the epidural or intrathecal space.²² The lumbar blocks leading to severe complications had been performed by anesthesiologists trained in this technique. It is thus unlikely that technical factors played a prominent role. Although it is still too early to draw any definite conclusion regarding this

block, anesthesiologists should be warned against the high rate of complications that was found with the posterior lumbar plexus block and should be advised to manage this block with at least the same vigilance as for a central block.

The incidence of systemic toxicity of local anesthetics and related seizures may also have been lower than in our previous report. Moreover, there were no cardiac arrests related to systemic toxicity. This low incidence of systemic complications may be related to better physician information and improved practice patterns (lower doses, slow injection, test dose, fractionated injection, and so forth). Although no local anesthetic-induced cardiac toxic event had been observed in our previous survey (at a time in which ropivacaine was not available in France), it is possible that the introduction of ropivacaine in clinical practice during this period has played a role, but this hypothesis cannot be verified using our methodology.

The incidence of neurologic complications after spinal anesthesia is higher with lidocaine than with bupivacaine. This supports the greater neurotoxicity of intrathecal lidocaine.²³⁻²⁵ Neurologic complications also occurred after peripheral nerve blocks. One main reason to support the use of a nerve stimulator is the perceived reduction in the risk of nerve trauma. The present study was not designed to address this issue, and the use of a nerve stimulator was not specifically mentioned for each peripheral block performed. The exact incidence of neurologic complications after nerve stimulation (*vs.* other techniques) thus cannot be calculated. However, several complications occurred despite the use of a nerve stimulator. Inadequate patient positioning and/or noncooperative patients, insufficient physician experience, insufficient patient information on the procedure, excessive sedation, or a nongentle technique are critical factors that increase the risk of neurologic complications, and this is certainly also true when a nerve stimulator is used. Moreover, several anesthesiologists continue to mobilize their needle until they have a distinct distal muscular movement with a very low electrical intensity (< 0.5 mA), because it is widely believed that the lower the intensity required, the closer the needle from the nerve and thus the higher the success rate. Although there are, indeed, data to support this view, this remains a controversial issue,²⁶⁻²⁸ and too small a distance between the needle and the nerve may in fact cause more harm than benefit. Further study is required to ascertain the role (or lack thereof) of these technical factors in the incidence of nerve injury during regional anesthesia.

In conclusion, this large-scale survey combining immediate declaration and analysis using a telephone hotline has allowed us to prospectively estimate the incidence of major complications after regional anesthesia. Several situations already known to be associated with an increased risk were identified (*i.e.*, spinal anesthesia-in-

duced cardiac arrest in the elderly or lidocaine toxicity after spinal injection). The major contribution is, however, the report of a high incidence of major complications after posterior lumbar plexus block and the occurrence of neurologic complications after the use of a nerve stimulator used for peripheral nerve blocks. A continuing survey will be useful because of the significant changes in practice that continue to occur.

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