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Serious Complications Related to Regional Anesthesia: Results of a Prospective Survey in France

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Abstract

Background: Serious complications related to regional anesthesia have previously been described primarily in case reports and retrospective surveys. The authors prospectively evaluated a multicenter series of regional anesthetics, using preplanned criteria to measure the incidence and characteristics of associated serious complications.

[Cited Here...](#): Requests were sent to 4,927 French anesthesiologists in advance of a subsequent 5-month study period. Participating anesthesiologists were asked for detailed reports of serious complications occurring during or after regional anesthetics performed by them during the study interval. Details regarding each complication then were obtained via a second questionnaire.

[Cited Here...](#): The number of responding anesthesiologists was 736. The number of regional anesthetics performed was 103,730, corresponding to 40,640 spinal anesthetics, 30,413 epidural anesthetics, 21,278 peripheral nerve blocks, and 11,229 intravenous regional anesthetics. Reports of 98 severe complications were received, with follow-up information being obtained for 97. In 89 cases, complications were attributed fully or partially to regional anesthesia. Thirty-two cardiac arrests, seven of which were fatal, occurred during the study. Of these, 26 occurred during spinal anesthesia, with 6 being fatal, 3 occurred during epidural anesthesia, and 3 more occurred during peripheral blocks. The higher incidence of cardiac arrest during spinal anesthesia (6.4 +/- 1.2 per 10,000 patients) compared with all other regional anesthesia (1.0 +/- 0.4 per 10,000 patients) was statistically significant ($P < 0.05$). Of 34 neurologic complications (radiculopathy, cauda equina syndrome, paraplegia), 21 were associated either with paresthesia during puncture ($n = 19$) or with pain during injection ($n = 2$), suggesting nerve trauma or intraneural injection. Twelve patients who had neurologic complications after spinal anesthetics had no paresthesia during needle placement and no pain on injection. Of these 12 patients (7 with radiculopathy and 5 with cauda equina syndrome), 9 received intrathecal hyperbaric lidocaine, 5%. The incidence of neurologic injury was significantly greater after spinal anesthesia (6 +/- 1 per 10,000 cases; $P < 0.05$) than after each of the other types of regional procedures (1.6 +/- 0.5 per 10,000 cases for the weighted average). Seizures attributed to elevated serum levels of local anesthetics occurred in 23 patients, but none suffered a cardiac arrest.

Conclusions: (1) The incidence of cardiac arrest and neurologic injury related to regional anesthesia were very low, but both were more than three SDs greater after spinal anesthesia than after other regional procedures. (2) Two thirds of the patients with neurologic deficits had either a paresthesia during needle placement or pain on injection. (3) Seventy-five percent of the neurologic deficits after nontraumatic spinal anesthesia occurred in patients who had received hyperbaric lidocaine, 5%.

Because it is rare for serious cardiac and neurologic complications to occur in association with regional anesthesia, published information regarding critical serious events are found primarily as retrospective studies or case reports. Few prospective surveys assessing large numbers of patients have been published. [1-3] Additionally, previous surveys did not record certain catastrophic events, such as cauda equina syndrome [4,5] and sudden cardiac death. [6] To estimate the incidence of serious complications now occurring with current drugs, equipment, and techniques, we conducted a prospective survey involving a large number of anesthesiologists. Our aim was to measure the incidence and the characteristics of serious cardiac and neurologic complications associated with regional anesthesia.

Methods

Study Design

Before the study there was a 3-week recruiting period. A copy of the protocol, a copy of a preliminary version of the final questionnaire, and a participation agreement form were sent to 4927 anesthesiologists practicing throughout France. To be a participating anesthesiologist in the study, physicians had to sign the agreement form and return it before the study period.

Participants who returned the agreement form were asked to keep a log for cases done between January 1, 1994 and May 31, 1994. In some medical centers, the log data gathered by participating anesthesiologists included cases in which they personally supervised anesthesiology residents or nurse anesthetists. However, in all such patients, anesthesia care was "medically directed" by the anesthesiologist, defined as in the United States: the attending anesthesiologist was present for the regional anesthesia procedure and for other crucial moments during surgery, and when absent, the attending anesthesiologist was available for immediate consultation or return to the operating room.

The log data contained the following information: (1) data about each case wherein regional anesthesia was performed, regardless of the type, and (2) data about each serious complication associated with regional anesthesia, with "serious complications" being predefined. Six "severe complications" were tallied: (1) cardiac arrest (no spontaneous breathing, no palpable pulse) requiring cardiac massage or epinephrine; (2) seizures; (3) radiculopathy; (4) cauda equina syndrome; (5) paraplegia; and (6) death. The final version of the questionnaire, i.e., the version used to obtain the data that were studied, was sent to all participating anesthesiologists 15 days before the end of the 5-month period.

The review of all questionnaires received was finished 30 days after closure of the study, at which time a follow-up questionnaire, specific to each type of serious event, was sent to participating anesthesiologists who reported complications. If the follow-up questionnaire was not received within 15 days, a telephone call was made to the participating anesthesiologist to directly obtain the follow-up information. Copies of all questionnaires used in the study, written in French, are available to readers, either immediately from the

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Follow-up questionnaires for all serious events were independently evaluated by three anesthesiologists, and reports of complications were reviewed to assure that they (1) adequately fit the definition of the complication; (2) occurred within an appropriate perioperative time period; and (3) were not wholly a result of either a preexisting medical condition or a cause obviously unrelated to regional anesthesia.

After the review by three anesthesiologists, reported complications were placed into one of three groups: (1) complications with too much missing information, (e.g., the follow-up questionnaire was incomplete); (2) complications unrelated to regional anesthesia, i.e., entirely explained by other etiologies; and (3) complications that were either completely or partially related to regional anesthesia. The frequency of complications was calculated from cases in the third category.

To compare demographic and professional characteristics of participating anesthesiologists with those of anesthesiologists who did not participate, a special questionnaire was sent to 200 randomly selected nonparticipating anesthesiologists.

In the tables and text, data that are approximately described by a normal distribution function are presented as mean \pm SD, whereas non-normally distributed data that are widely skewed are presented by giving the median and values corresponding to the 25th and 75th percentiles. Pearson's chi-square test was used for dichotomous categorical data. When the distribution was not normal, a Mann-Whitney test was used. A Student's t test was used to compare continuous data. [7] When an approximately normal distribution was seen, formulae based on the normal distribution [7] were used to calculate 95% confidence intervals for the incidence of serious complications. When the distribution was not normal, tables of the Poisson Distribution [8] were used.

Results

Participation in the study was agreed to by 736 of the 4,927 anesthesiologists (14.9%) who were contacted. The participants reported 103,730 regional anesthetics during the 5-month study period. This included 40,640 spinal anesthetics, 30,413 epidural anesthetics, 21,278 peripheral nerve blocks, and 11,229 intravenous regional anesthetics. Sixty nonparticipating anesthesiologists replied to the second questionnaire. Demographic data for participating and nonparticipating anesthesiologists are given in [Table 1](#), which shows that the two groups were comparable, except that the nonparticipating group contained a higher percentage of anesthesiologists who never performed regional anesthesia during the study period. No complications were reported by the nonparticipating group. Among the 736 participants, 95 physicians reported 98 serious complications. Private practitioners performed more cases of regional anesthesia and were more likely to report complications. For some of the results in

[Table 1](#) regarding participating and nonparticipating anesthesiologists, such as the number of cases reported per participant, the data do not have a normal distribution, and the range of the results (25th to 75th percentiles) is given below the mean value. The departure from a normal distribution originates from the fact that some responding anesthesiologists supervised residents or nurse anesthetists, as mentioned previously. These participants could sometimes conduct more cases per day than one anesthesiologist working alone, with their reports reflecting work done by more than one person.

Table 1

The follow-up questionnaire was answered by 94 of the 95 anesthesiologists who reported complications. Data were obtained by mail from 67 participants and by telephone from 27 participants. A follow-up analysis was done for 97 of 98 reported complications. The incidence of different critical serious events is presented in [Table 2](#). Eight of the 97 complications were considered unrelated to regional anesthesia. The incidence of complications related to each regional anesthetic technique is given in [Table 3](#). Additional details regarding specific types of complications will be discussed.

Table 2

Table 3

Cardiac Arrest

The incidence of cardiac arrest was significantly greater with spinal anesthesia (6.4 +/- 1.2 per 10,000 patients) than with epidural anesthesia and peripheral nerve blocks combined (1.0 +/- 0.4 per 10,000 patients; $P < 0.05$, see [Table 3](#)). During the 26 cardiac arrests occurring with spinal anesthesia, 15 patients were treated only with closed-chest cardiac massage and ephedrine; one patient was treated only with epinephrine (0.5 mg); and 10 patients were treated with closed chest cardiac massage and epinephrine (3.4 +/- 3.6 mg).

Fatal outcome from cardiac arrest occurred in 6 of the 26 cardiac arrests. Risk of death after cardiac arrest was significantly associated with age and American Society of Anesthesiologists' (ASA) physical status class. The average age of survivors was 57 +/- 20 yr,

whereas the average age of nonsurvivors was 82 +/- 7 yr. The difference in average ages was statistically significant ($P < 0.05$). Similarly, the breakdown of ASA physical status for survivors versus nonsurvivors was $n = 13$ versus $n = 0$ for ASA I; $n = 5$ versus $n = 2$ for ASA II; $n = 2$ versus $n = 3$ for ASA III; and $n = 1$ versus $n = 0$ for ASA IV. Two variables were statistically different regarding cardiac arrest in patients undergoing spinal anesthesia: (1) the time between onset of spinal blockade and occurrence of cardiac arrest was longer in non-survivors than in survivors (42 +/- 19 min versus 17 +/- 16 min, respectively; $P < 0.05$); and (2) total hip arthroplasty (THA) more frequently was the type of surgery in nonsurvivors than in survivors (5 of 6 THA among nonsurvivors compared with 2 of 20 non-THA surgeries in survivors; $P < 0.05$). During THA, three cardiac arrests happened at the time of cement insertion and were fatal. Blood loss at the time of cardiac arrest was 700 ml in nine cardiac arrest patients, with four arrests being fatal. Sedation was not performed nor was cyanosis or dizziness observed before any of the fatal cardiac arrests, although all cardiac arrests were reported to have been preceded by bradycardia. Three cases of reversible cardiac arrest were reported with epidural anesthesia. Three cases of cardiac arrest were reported during peripheral nerve blocks. In each case, these appeared to be associated with inadequate analgesia. In two of the three cases, cardiac arrest also was associated with vasovagal responses, treated, and reversed. One fatal cardiac arrest resulted from a myocardial infarction. No neurologic sequelae were observed in the 25 patients who recovered from cardiac arrest.

Neurologic Complications

All 34 neurologic complications presented within 48 h of surgery. Neurologic sequelae were considered permanent if they lasted more than 3 months. These occurred in five patients. Twenty-nine patients had transient sequelae, with recovery occurring between 48 h and 3 months.

([Table 3](#)) summarizes the findings and shows a higher incidence of neurologic injury after spinal anesthesia (6 +/- 1 per 10,000 cases) than after the other techniques combined (1.6 +/- 0.5 per 10,000 cases): epidural anesthesia, peripheral nerve block, or intravenous regional anesthesia. Radiculopathy was more frequently observed after spinal than after epidural anesthesia ([Table 3](#)). In 12 of 19 cases of radiculopathy after spinal anesthesia and in all cases of radiculopathy after epidural anesthesia ($n = 5$) and peripheral blocks ($n = 4$), needle puncture was associated either with paresthesia during puncture ($n = 19$) or with pain during injection ($n = 2$). In all cases, radiculopathy had the same topography as associated paresthesias. Anesthesiologists did not continue to inject when pain on injection occurred. All patients with neurologic deficits lasting more than 2 days were examined by a neurologist. All patients with cauda equina syndrome had a computed tomography (CT) scan to rule out a compressive etiology. In 12 patients in whom neurologic deficits occurred after spinal anesthesia, there was paresthesia or pain during injection. In these patients, hyperbaric bupivacaine, 0.5%, was used in 11 patients, whereas hyperbaric lidocaine, 5%, was used in one patient. All patients with radicular deficits after paresthesia recovered, although a permanent neurologic deficit occurred in one patient who had a paresthesia during

placement of the spinal needle but no pain during the subsequent intrathecal injection of 15 mg of hyperbaric bupivacaine, 0.5%.

Thirteen neurologic complications were not associated with pain, paresthesias, or technical difficulties. Twelve of these occurred after spinal anesthesia, with 9 of 12 patients having received hyperbaric lidocaine, 5%, intrathecally. Eight of the nine patients received a single dose of 75-100 mg of lidocaine. Two of the eight had permanent radiculopathy or cauda equina syndrome. One of the nine patients underwent continuous spinal anesthesia via an infusion of lidocaine, 5%. That patient received 350 mg of lidocaine over 5 h, and had permanent cauda equina syndrome. Three patients received 12-20 mg of hyperbaric bupivacaine, 0.5%, and had only transient neurologic deficit.

One case of paraplegia occurred in a patient aged 62 years who underwent a combined technique: an uneventfully placed epidural block followed by general anesthesia. Lidocaine, 2%, without epinephrine was used. This patient had intraoperative hypovolemic arterial hypotension. Result of a CT scan of the lumbar spine, taken 1 day after surgery to rule out a compressing hematoma, was normal.

Seizures

All 26 reported seizures were preceded by minor auditory symptoms and complaints of metallic taste. The more frequent occurrence of seizures after peripheral block than after epidural anesthesia was statistically significant ([Table 3](#)). In patients who suffered a seizure, a larger volume of lidocaine, 2%, or bupivacaine, 0.5%, was injected for peripheral nerve blocks (41 +/- 14 ml) than for epidural anesthesia (15 +/- 4 ml). This difference is statistically significant ($P < 0.05$). Although bupivacaine was injected in 14 of the 23 patients having seizures after epidural anesthesia or peripheral nerve blockade, it was never associated with cardiac arrest, either when used alone, or when used in combination with lidocaine. During intravenous regional anesthesia, three seizures were reported to have occurred after deflation of the tourniquet. In each of those patients, tourniquet inflation after injection of 30-45 ml of lidocaine, 0.5%, exceeded 40 min. In 23 patients, seizures were treated by intravenous administration of midazolam at the same time that supplemental face mask oxygen was provided. In three patients, thiopental was administered and followed by tracheal intubation.

Discussion

Because we were able to include 103,730 regional anesthetic procedures, our approach was successful in obtaining sufficient prospective data for the investigations. Because serious complications after regional anesthesia are rare, large numbers of patients are required to compare the incidence and characteristics of critical serious events. For example, if one technique has twice as many critical serious events as another, enough cases should be studied to result in approximately 30 and 15 adverse events, respectively, for the two methods, thereby determining incidences that are three SDs apart. If the incidence of a

critical serious event is 0.1% and if critical serious events often occur at a lower incidence, 30,000 cases must be studied to encounter 30 critical serious events. Thus, studies like ours should carefully choose the large number of patients that will be enrolled. Studying too few patients provides results having too little discriminatory power. Studying too many patients requires unaffordable luxuries in funding and time. Despite the absence of an official list of French anesthesiologists, use of a private list permitted us to reach 75% of all working French anesthesiologists. Although participation was only 14.9%, this figure is comparable with that achieved in other surveys. [\[9\]](#) More significantly, we note that the demographic data of participants were comparable with data representative of all anesthesiologists in France.

Because it was not practical to extensively audit patient charts postoperatively, quality control of information regarding critical serious events was a concern focused on at two levels: (1) by the three anesthesiologists as they reviewed follow-up questionnaires; and (2) by all authors after the reviews were complete. In some instances, individual case logs were inspected at random times by some of the authors during incidental visits to the institutions of participating anesthesiologists. Such individual logs were always found to conform to the protocol, but a systematic approach to checking the logs was not conducted. Nevertheless, the self-consistency of reports, the prospective character of the study, the voluntary participation and work ethic of the anesthesiologists, the focus on rare serious complications, and the confidential, nonaccusatory style of data gathering caused us to conclude that the collected information was reliable and complete.

Because the average number of regional anesthetics performed each month by participating anesthesiologists was 29, in contrast to an average of 16 per month performed by nonparticipating anesthesiologists, participating anesthesiologists appear to be more experienced in the performance of regional anesthesia. (This was the only significant difference we found between the two populations, and we note that some participating anesthesiologists supervised residents and nurse anesthetists, which might have amplified their frequency of performed regional procedures.) This also suggests there is no rational basis for assuming that nonparticipating anesthesiologists should be expected to have a lower complication rate.

The incidence of complications reported in this study is comparable with those found in various other surveys of radicular deficits, [\[1,10\]](#) cardiac arrest, [\[11\]](#) and seizures [\[13\]](#) after spinal or epidural blocks. Caplan et al. [\[6\]](#) reported 14 cases of fatal cardiac arrest during spinal anesthesia. Sedation was found as a risk factor in 12 of those patients, whereas bradycardia was cited as an initial factor in 7. In contrast, in our patients sedation was not present in any patient before fatal cardiac arrest, and bradycardia preceded all cases of cardiac arrest. One possible explanation for this difference in critically serious events is that Caplan et al. [\[6\]](#) retrospectively studied cases of relatively young, healthy patients who had cardiac arrest, severe neurologic sequelae, or death after regional anesthesia. In contrast, we prospectively studied randomly chosen patients in a population representative of wide-spread daily practice. A different recent survey reported neurologic complications after

spinal anesthesia and epidural anesthesia in a Swedish University Hospital. ^[2] This study, which was only in part prospective, found comparable rates of adverse neurologic sequelae after spinal anesthesia, but a higher rate of neurologic complications after epidural anesthesia.

Although cardiac arrest and neurologic injury occurred more often in our study after spinal anesthesia, this finding should be interpreted cautiously. First, factors not pertaining to regional anesthesia that were found in our study as associated to fatal outcome after cardiac arrest might also explain the increased incidence of cardiac arrest during spinal anesthesia. These include advanced age, ASA physical status (or preexisting disease), time after injection, surgical trauma and blood loss, and type of surgery, such as THA. In contrast, because of differences in sizes of needles and volumes of injected medications, risks of neurologic injury might depend less on factors just listed and depend more on the type of regional anesthesia. Because of the low incidence of complications, as discussed previously, it might never be possible to get sufficient numbers of study patients for every ASA class, every type of surgery, or every subgroup one may want to compare.

Because all seizures occurring after epidural anesthesia, peripheral nerve block, and intravenous regional anesthesia were preceded by premonitory signs, they were probably a result of acutely increased systemic concentration of local anesthetics. The incidence of seizures in our study is comparable with those observed in other studies. ^[13] Seizures after peripheral nerve block were five times more frequent than after epidural anesthesia. This difference might be explained by the fact that peripheral blocks generally require larger doses of local anesthetics than epidural anesthetics. Seizures after tourniquet release after intravenous regional anesthesia occurred despite the use of a standard dose of lidocaine and a long duration of tourniquet inflation.

Although previous reports found that bolus intravenous injections of bupivacaine were associated with cardiotoxicity leading to cardiac arrest, ^[14] no cardiac arrests were observed in our study in conjunction with bupivacaine. Similar absence of primary cardiac arrhythmia as a result of local anesthetics was recently reported. ^[13]

Current controversies regarding the cytotoxicity of local anesthetics ^[15-18] draw special attention to the 12 patients who developed radiculopathy or cauda equina syndrome after uneventful spinal anesthesia. In each of these patients, subarachnoid delivery occurred without paresthesia or pain on injection. In 9 of 12 patients, hyperbaric lidocaine, 5%, was used. Because we do not know the relative use of hyperbaric lidocaine, 5%, and hyperbaric bupivacaine, 0.5%, for spinal anesthesia by the 736 anesthesiologists who participated to our study, it is difficult to interpret this finding. However, hyperbaric bupivacaine, 0.5, was used more frequently than hyperbaric lidocaine, 5%, in patients who developed radiculopathy after spinal anesthesia and paresthesia or pain (11 vs. 1). Also, during the study period, the consumption of hyperbaric local anesthetics in France by anesthesiologists was 72,300 2-ml ampules of lidocaine, 5%, and 199,780 4-ml ampules of bupivacaine, 0.5%, permitting

speculation that hyperbaric lidocaine, 5%, might have been used less often for spinal anesthesia and therefore might somehow have been associated with a higher incidence of the neurotoxicity that is rarely seen with that type of block, even though the dose and the technique are standard. This is probably the main difference between our findings and previous reports of cauda equina syndrome. [\[4\]](#)

The only case of paraplegia observed in our study occurred in an elderly patient who were given epidural anesthesia and general anesthesia. The most probable cause was spinal cord ischemia as a result of prolonged hypotension. That none of the spinal or epidural anesthetics resulted in an epidural or subarachnoid hematoma may have been a result of, in part, compliance with recommendations of a recent French consensus conference that proposed avoidance of spinal or epidural anesthesia in patients who are taking anticoagulants preoperatively.*

In summary, the incidence of severe, anesthesia-related complications in regional anesthesia is very rare, substantially less than 0.1%. Further studies with larger numbers of patients would be required to accurately assess the relative risks of physical status, type of surgery, and use of hyperbaric lidocaine, 5%, for spinal anesthesia. However, in this study we found a higher incidence of cardiac arrest and neurologic injury for spinal anesthesia, perceived by many anesthesiologists as simple and safe, than for the other forms of regional anesthesia. A comparison of the relative incidence of cardiac arrest for the two techniques has not been studied previously. However, we reiterate that a disproportionate risk for cardiac arrest might be heavily associated with factors other than regional anesthesia, whereas a higher risk of neurologic injury might be primarily associated with the type of regional anesthesia procedure being performed.

The authors thank the 736 participating anesthesiologists and all who helped them, not only for obtaining and providing the data for this study, but also for their enthusiasm, encouragement, numerous suggestions, and cooperation via meticulous adherence to protocols. Their belief in the importance of this effort was the driving force, "le moteur," which made it all possible.

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