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Research Article

Complications and outcomes following central neuraxial anesthesia in a sub-Saharan Tertiary Hospital: The legal implication

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KEYWORDS

Central neuraxial anesthesia;
Complications;
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Abstract *Background:* Complications following central neuraxial anesthesia have led to litigations and claims in developed nations, however, the incidence of litigation is low in our environment. Anesthetist practicing in Nigeria need to be aware that such complications are not uncommon.

Aim and objective: To determine central neuraxial anesthesia related complications and the legal implications.

Method: This was a prospective observational study conducted in 821 patients scheduled for surgery under central neuraxial anesthesia from February 2012 to January 2013. The choice of anesthesia depended on the indication and the duration of surgery.

Results: The observed complications of central neuraxial anesthesia, which may result in litigation included inadvertent high block (22.4%), paresthesia during needle placement (6.2%), inadequate block (3%), failed block (1.2%), and postdural puncture headache (1.15%). Others were seizure (0.1%), meningism (0.1%), persistent pain in the lower limb for 48 hours (0.1%), back pain (0.7%) and cardiac arrest (0.49%); three of the four cardiac arrest died. There was, however, no report of litigation or claim in this study.

Conclusion: We have demonstrated that complications, which may result in litigation and claim following central neuraxial anesthesia is not a rare occurrence in our institution. However, there was no record of litigation or claim in our review. Anesthetist in Nigeria need to be aware of the

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legal implication of such complications. When performing blocks, well recognized complications should be discussed before obtaining consent. If any untoward effect occurs, a detailed note of the findings and treatment should be documented for future reference.

1. Introduction

Complications arising from central neuraxial anesthesia, which had resulted in litigations and claims in developed nations such as United States, Canada and Europe included cardiac arrest, paresthesia during needle placement, permanent nerve injury, postdural puncture headache and back pain [1–3]. Data on anesthesia safety are often derived from closed claims registry, rather than from peer review and internal or external audits, which could provide detailed and precise information [4]. One-fifth of anesthesia related professional liability claims resulted from regional anesthesia; most of which were temporary, with approximately one-half associated with anesthesia [1,5]. The claims were related to poor technique in 25% of litigations, neuraxial related cardiac arrest (8%), permanent nerve injury (36%), inadequate anesthesia or analgesia (5%), high spinal or epidural block (4%), malfunctioning epidural catheter (3%) and unintentional intravenous injection of local anesthetic agent (3%) [5]. High severity injuries are those with the highest compensations, they included neuraxial related cardiac arrest, neuraxial hematoma, and permanent nerve injury [1,2,5]. It has been suggested that increased vigilance on the part of the attending anesthetist, with prompt diagnosis, and appropriate intervention may improve outcome in high severity injuries [1,5].

The American Society of Anesthesiologists (ASA) Closed Claims Registry was started in 1985 to study anesthesia related injuries, to improve patient safety, identify major areas of loss in anesthesia and to analyze the patterns of injury following anesthesia related litigations in the general courts. This is expected to reduce patient injuries, malpractice claims and consequent payments, thereby leading to a decrease in professional indemnity premiums [1,5]. The Medical and Dental Practitioners Act 1990 (Decree No. 23 of 1988), AP 221 Law of Federation of Nigeria (LFN), now LFN 2004 is an Act, which established the Medical and Dental Council of Nigeria Act, established as an arbitration panel to provide a Disciplinary Tribunal for the discipline of erring members [6]. This is the platform where complaints are filed by patients or their relations. In Nigeria, though reports of complications following central neuraxial anesthesia are not rare [7,8], litigations and claims seem to be uncommon. This study investigated the complications, which may follow central neuraxial anesthesia, and determined if this was accompanied by litigation.

2. Patients and methods

This was a cohort study of 821 patients scheduled for surgery under central neuraxial anesthesia from February 2012 to January 2013. After Ethical committee approval and informed consent were obtained, all patients that fulfilled the inclusion criteria were recruited. The exclusion criteria included standard contraindications to central neuraxial anesthesia, known allergy to any of the amide local anesthetic agents, and patients in whom it was not possible to adequately assess neuraxial block level.

2.1. Anesthetic procedure

Routine investigations were done in all patients prior to surgery, according to hospital guidelines. On arrival in theater a multi-parameter monitor was attached, and baseline vital signs were measured. Routine monitoring was continued during the perioperative period. Spinal anesthesia, lumbar epidural anesthesia, or combined spinal-epidural anesthesia was performed by the attending anesthetist based on the patient's need. Central neuraxial anesthesia was established in the sitting position in all patients.

All patients for spinal anesthesia had preload with 0.9% normal saline (10 ml/kg) over 20 min. Spinal anesthesia was induced with 0.5% heavy bupivacaine (11–17.5 mg), Marcain AstraZeneca UK, with or without a preservative free fentanyl 25 μg into the subarachnoid space in the lumbar third/fourth (L_3–L_4) or fourth/fifth (L_4–L_5) interspace using a 26 gauge pencil tip spinal needle via an introducer.

In the patients who received epidural anesthesia, epidural catheter was inserted into the lumbar third/fourth (L_3–L_4) or fourth/fifth (L_4–L_5) interspace using the loss of resistance to saline technique via a 16/18G Tuohy needle. After the depth of the epidural space was noted, 3–4 cm of epidural catheter was inserted. A test dose of 4 ml of preservative free 1% lidocaine in 1:200,000 epinephrine (Rotex Medica, Trittau Germany) was injected to exclude intrathecal or intravenous catheter insertion. Epidural anesthesia was initiated with the injection of 0.5% plain bupivacaine (25–50 mg), Marcain Astra Zeneca UK, into the epidural space after negative aspiration for blood and cerebro-spinal fluid. Thereafter, boluses of 0.5% plain bupivacaine (12.5–25 mg) were administered till the end of the operation after a two segment regression in sensory block from the desired dermatome level.

In patients who had combined spinal epidural anesthesia; the double needle-separate interspace technique was used. Two intervertebral spaces were localized, (L_3/L_4) and (L_4/L_5) interspaces. The epidural catheter was inserted at (L_3–L_4) interspace, and the spinal anesthesia at (L_4–L_5) interspace. Epidural anesthesia was instituted one hour after spinal anesthesia with 0.5% bupivacaine 15–30 mg after negative aspiration for blood and cerebro-spinal fluid. Epidural top up was administered as outlined above.

Immediately after establishing the block, the patients were re-positioned supine, and the level of the block was confirmed using the loss of sensation to pin prick. All patients remained in the recumbent position until the sensory level progressed to a dermatome level appropriate for the surgical procedure. The sensory block level was checked using pin prick, and it was recorded, every 2.5 min for 25 min. Thereafter, the assessment

was continued at 20 min interval throughout the surgery. Motor block was assessed using the modified Bromage scoring system. If a patient complaint of discomfort during surgical manipulation, IV midazolam (0.02 mg/kg) was given as a bolus. Spinal or epidural anesthesia was converted to general anesthesia in patients who developed high or failed block. Hypotension was recorded and treated with IV fluids, with or without IV boluses of ephedrine as clinically appropriate. Bradycardia was recorded and treated with IV atropine 600 μg.

Upon arrival in the post-anesthesia care unit, monitoring was continued. The modified Bromage score and sensory block level were assessed until complete resolution of motor block, and regression of sensory block to sacral dermatome (S_2). On the first and second day after surgery, the researcher visited the patient and inquired about the presence of any postoperative problems; in particular for the existence of postdural puncture headache (PDPH), and transient neurological syndrome. Data collated included demographic and clinical parameters, type of surgery or anesthesia, treatment modalities, and complications. Information on litigation was obtained from the anesthetist involved in a major complication, and an inquiry was made with the medical and dental council of Nigeria on any anesthesia related report or misconduct with the council.

2.2. Statistical analysis

Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) for windows 20 computer Software Program. Results were presented as mean ± SD, frequency and percentage. The Chi-square was used for categorical data.

3. Results

A total of 821 patients were studied; with a median age of 33, 25th–75th quartile range (29–39) years, female patients were 733(89.3%), and 548(66.7%) were obstetrics. The most common anesthesia technique was spinal anesthesia in 655(79.78%) patients, followed by combined spinal epidural anesthesia in 125(15.22%) patients. The median year of experience of the attending anesthetist was 3 years, 25th–75th quartile range, (2.4–5) years; 523(63.70%) of the anesthesia were performed by an anesthetist with an experience of five years and above. Two anesthetists with less than six months exposure established spinal anesthesia under senior supervision, Table 1.

There were 1124 attempts at establishing a spinal and, or, epidural anesthesia; 625(55.60%) were successful at the first attempt, 276(24.56%) at the second attempt, and 223(19.84%) required three or more attempts, two of whom were converted to general anesthesia. In a 68 year old man, a known hypertensive with lumbar scoliosis scheduled for urethroplasty who developed profound hypotension (SBP 80 mmHg), and fainting attack secondary to vasovagal shock after six attempts at localizing the epidural space. The procedure was postponed after successful resuscitation with IVF Isoplasma and IV ephedrine 0.1 mg/kg.

There was a significant association between the number of attempts at anesthesia, and the frequency of some untoward events such as traumatic block, accidental dura puncture, failed block, lower limb pain, or back pain, ($p < 0.05$) Table 2. The frequency of complications, however, decreased with an increase in the years of experience of attending anesthetist (five years and above), Table 3.

The complications which occurred after central neuraxial anesthesia are detailed in Table 3. Some patients had more than one complication; 721 complications were observed in 821 patients, (incidence of 87.82%). The most common complications were hypotension 38.2% and inadvertent high block 22.4%, Table 4. Cardiac arrest was observed in four patients (0.49%), among whom three died.

Spinal and, or, epidural anesthesia related complications included paresthesia, high sensory block level, PDPH, and meningism. Cardiac arrest was, however, unrelated to the technique of anesthesia; (postmortem examination revealed amniotic fluid embolism in one patient, and massive hemorrhage in another, while the third patient refused postmortem). Hypotension, bradycardia, inadvertent high block, and inadequate block were significantly more in the obstetric patients, Table 5. There were no documented litigation or court proceeding resulting from these complications.

4. Discussion

Litigable complications were not uncommon in our center, despite this there was no reported case of litigation and claim. We also observed that none of the high severity injuries were

Table 1 The distribution of central neuraxial anesthesia by the cadre and experience of the attending anesthetist.

Variables	Types of central neuraxial anesthesia		
	Spinal (n = 655) (%)	Lumbar epidural (n = 41) (%)	Combined-spinal epidural (n = 125) (%)
Cadre of anesthetist			
Consultant (n = 48)	4.27	19.51	9.6
Senior registrar (n = 685)	84.58	75.61	80
Junior registrar (n = 86)	10.83	4.88	10.4
Postgraduate diploma trainee (n = 2)	0.32	0	0
Anesthetist years of experience			
⩾5 years (n = 523)	62.14	65.85	71.2
<5 years (n = 298)	37.86	34.15	28.8

Values are percentage.

Table 2 The association between the number of attempts at establishing central neuraxial anesthesia and the complications rates.

Complications	Number of attempts			*p* Value
	One (n = 625) (%)	Two (n = 138) (%)	⩾Three (n = 58) (%)	
Cardiovascular				
Cardiac arrest	0.32	0.72	1.72	0.309
Neurological				
Seizure	0.16	0	0	0.855
Meningism	0.16	0	0	0.855
Postdural puncture headache	1.28	2.17	1.72	0.720
Accidental dura puncture	0.16	0	1.72	0.567
Paresthesia during needle placement	8.16	2.46	34.48	<0.001
Lower limb pain for 48 h	0	0	1.72	0.001
Back pain	0.48	0.72	8.62	<0.001
Techniques related				
Difficulty in identifying space	2.72	13.77	79.31	<0.001
Difficulty in advancing needle	0.96	7.97	62.07	<0.001
Difficulty in obtaining CSF	1.6	10.15	24.14	<0.001
Traumatic block	1.92	10.14	51.72	<0.001
Accidental dura puncture	0	0	1.72	0.001
Failed block	0.32	3.62	5.17	<0.001

Values are percentage, p value ⩽ 0.05 was considered significant.

Table 3 The association between anesthetist years of experience and complications.

Complications	Years of experience		*p* Value
	⩾5 years (n = 523) (%)	<5 years (n = 298) (%)	
Cardiovascular			
Cardiac Arrest	0.38	0.67	0.568
Neurological			
Paresthesia during needle placement	4.78	8.72	0.024
PDPH	1.34	1.68	0.697
Lower limb pain for 48 h	0	0.34	0.364
Back pain	0.76	1.68	0.016
Seizure	0.19	0	0.318
Techniques related			
Difficulty in identifying space	3.25	6.38	0.001
Difficulty in advancing needle	4.78	11.07	0.007
Traumatic block	4.97	10.07	0.005
Difficulty in obtaining CSF	2.1	6.04	0.003
Accidental dura puncture	0.19	0	0.450
Failed block	1.15	1.34	0.806

Values are percentage, p value ⩽ 0.05 was considered significant.

reported to the Nigerian Medical and Dental Council. Furthermore, there were no data on anesthesia related complaints lodged with the council since its inception [6]. We attributed our observation to the cultural and religious belief of the people, because such occurrences are considered the "will of God." This may significantly reduce the incidence of litigations, unlike in developed nations.

Cardiac arrest, death, inadvertent high block, failed block, inadequate anesthesia or analgesia were litigable complications observed during our investigation. Others included paresthesia during needle placement, persistent pain in the lower limb for 48 h, back pain, meningism and PDPH. The development of some of these complications has been linked to the technique of central neuraxial anesthesia, which is related to the level of competence of the attending anesthetist. On the contrary, high severity complications have resulted in litigations and claims in developed nations [1–3].

In our review, though 63.70% of the central neuraxial anesthesia was established by an anesthetist with more than five years' experience. The first attempt success rate (55.60%) was within the range of 44.7–87.3% reported in other studies [9,10]. In 19.84% patients with three or more attempts at spinal or epidural anesthesia; among of whom a 68 year old hypertensive with lumbar scoliosis scheduled for urethroplasty under epidural anesthesia developed vasovagal hypotension (SBP 80 mmHg) after the sixth attempt of inserting a 16G

Table 4 The complications following central neuraxial anesthesia in a surgical population.

Types of complications	Frequency (n = 821)	Percentage (%)	Litigable events
Cardiovascular			
Hypotension	314	38.2	No
Bradycardia	62	7.6	No
Cardiac arrest	4	0.5	Yes
Central nervous system			
Seizure	1	0.1	Yes
Meningism	1	0.1	Yes
Postdural puncture headache	12	1.5	Yes
Paraesthesia during needle placement	51	6.2	Yes
Lower limb pain for 48 h	1	0.1	Yes
Back pain	9	1.1	Yes
Technique of anesthesia			
Inadequate block	25	3	Yes
Failed block	10	1.2	Yes
Accidental dura puncture	1	0.1	Yes
Inadvertent high block	184	22.4	Yes
Nausea and vomiting	26	3.17	Yes
Nasal pruritus	10	1.2	Yes

711 complications in 821 regional anesthesia, some patients had more than one complication.
Values are frequency and percentage.

Table 5 The comparison of complications between obstetric and non-obstetric patients.

Complications	Obstetrics (n = 548) (n = 548)	Non-obstetrics (n = 273) (n = 273)	Degree of freedom	p Value
	(%)	(%)		
Cardiovascular				
Hypotension	42.15	30.4	1	0.001
Bradycardia	64.58	11.36	1	0.004
Cardiac arrest	0.73	0	1	0.157
Neurological				
Seizure	0.18	0	1	0.259
Meningism	0.18	0	1	0.480
PDPH	0.91	2.56	1	0.063
Accidental dura puncture	0	0.37		0.567
Paresthesia during needle placement	5.66	7.33	2	0.496
Lower limb pain for 48 h	0.18	0	2	0.366
Back pain	1.28	0.73	1	0.282
Techniques related				
Inadequate block	2.19	4.76	3	0.005
Failed block	1.28	1.09	1	0.826
Accidental dura puncture	0	0.37	2	0.496
Inadvertent high block	31.75	3.66	3	0.005
Nausea and vomiting	3.47	2.56	2	0.496
Nasal pruritus	0.73	2.19	2	0.153

Values are percentage, p value $\leqslant 0.05$ was considered significant.

Tuohy needle. However, he was successful resuscitated with 500 ml of Isoplasma and IV ephedrine 0.1 mg/kg, thereafter, the surgery was rescheduled. This is an indication that multiple attempts at inserting spinal or epidural needle should be discouraged, as this has been associated with adverse events [9,10]. The National Institute for Clinical Excellence has recommended the use of ultrasound guidance for catheterization of the epidural space when there are technical difficulties in identifying the epidural space [11].

There was a significant association between some untoward events such as traumatic block, accidental dura puncture, failed block, lower limb pain, or back pain, and increase number of attempts during spinal, and, or epidural anesthesia in our study. A similar pattern of observation was also noted with years of experience less than five years. However, there are conflicting reports on the influence of year of experience on complications during spinal or epidural anesthesia, while some believe there is an association [7,10], other researches

has refuted this view in their study [9]. The evaluation of the association between the years of experience of the attending anesthetist and various litigable complications might give an insight into the quality of anesthesia care, allow preventive measures to be instituted, and provide direction for future research. There is a need for proper supervision of trainees, and continuous evaluation or audit of events which might contribute to litigable complications during spinal or epidural anesthesia.

In a randomized controlled trial predicting factors which influence the success of spinal anesthesia during urological procedures using a spinal difficulty score [9]. The authors observed that when calculating the difficulty score before spinal anesthesia, grade 4 is the value at or above which the score is indicative of difficulty with or without the lumbar vertebral radiological characteristics. They reported a significant association between the spinal bony landmarks and radiological characteristics of the lumbar vertebrae, and the number of attempts, the level of sensory block and success of the spinal analgesia. However, the experience of the anesthetist had a significant impact only on the number of attempts and levels of block, but not the success of the spinal analgesia [9]. The authors encouraged the use of a preoperative difficulty score to predict difficulty before spinal anesthesia. In their review, the most senior anesthetist performed the spinal anesthesia after four attempts [9]. In contrast, Kim et al. [10], observed that the provider's level of experience and the distance from skin to subarachnoid or epidural space were significant predictors of difficulty during spinal or epidural anesthesia. The authors suggest that the epidural and subarachnoid spaces should be identified at the first attempt, since multiple punctures increase the risk of postdural puncture headache, epidural hematoma and neural trauma [10].

Direct needle trauma is often implicated in minor neurological problems [1,12]. This is evident in one of our patients who reported paresthesia during needle insertion, and later developed persistent pain in the lower limb for a duration of 48 h. Our observation is in-line with a previous report, where two-thirds of their patients with radiculopathy after spinal anesthesia, as well as all patients with radiculopathy after epidural anesthesia and peripheral nerve block had a positive history of either paresthesia at the time of needle puncture or pain during injection of local anesthetic agents [13]. The low incidence of temporary neurological injury in our report may be related to the teaching in our center, which encourage withdrawal of the spinal needle whenever there is a complaint of paresthesia during needle insertion.

The incidence of inadvertently high block (22.4%) was more in our investigation than in previous documentation (4%) [5]. The difference in dosage of local anesthetic agent administered in the studies may be responsible. The low incidence of PDPH in our review is likely related to the use of 26 gauge pencil point spinal needles. The size of the spinal needle has been implicated in the development of PDPH [1]. Transient neurological syndrome or cauda equina syndrome was not observed in our study. Transient neurological syndrome was reported in ten patients after cesarean section under spinal anesthesia in Eastern Nigeria [7]. The implicated risk factors were the use of cutting spinal needle (Quincke), increased number of attempts at lumbar puncture and the grade of anesthetists who performed the block [7]. The use of 5% lidocaine or steroids has been implicated in the development of neurological complications [1,5]. In our review, the observed complications related to central neuraxial anesthesia were commoner in the obstetric population, this was the trend in previous documentations [2,6]. This may be related to the physiological changes during pregnancy that increase sensitivity to local anesthetic agent, and reduce the epidural space volume. This arises from an enlargement of the epidural veins, as well as the increase intra-abdominal pressure of pregnancy, which may displace cerebro-spinal fluid from the thoracolumbar region of the subarachnoid space, and lower specific gravity of cerebro-spinal fluid in pregnant patients than in non-pregnant women [14].

Other risk factors implicated in the development of major neurological complications following central neuraxial anesthesia include the presence of hypotension, anticoagulation, preexisting neurological condition and arteriosclerosis [15,16]. The absence of spinal or epidural hematoma in this review may be related to the exclusion of patients with coagulopathy, and also the strict adherence to the guideline for central neuraxial anesthesia in patients on anticoagulation therapy. A higher incidence of hematoma was, however, reported in ASA close claims in the 1980s and 1990s, when such strict guidelines did not exist [1,2].

Our finding of four cardiac arrest (0.49%), out of whom three died surprisingly was unrelated to the spinal anesthesia, unlike in the closed claim project reports [1,2]. Postmortem report on two of the patients' revealed amniotic fluid embolism and massive hemorrhage. The third patient's next of kin refused a postmortem review on religious grounds. The issue of religious belief has been a major factor mitigating against proper documentation and litigation in Nigeria.

In contrast to our report, in developed nations where close claims projects are established, there were reports of litigations and claims [1,2,5]. In ASA close claims registry database of the 1980s and 1990s, it was reported that 443 out of 6894 patients (6.43%) who received central neuraxial anesthesia filed litigation against their anesthetist [1,5]. The Canadian close claims reported that 13–20.6 per 1000 anesthetist were involved in litigations [2]. There has been no anesthesia related cases reported to the Nigerian Medical and Dental council since its inception [6]. It has been observed that only a small percentage of adverse outcomes result in a claim being filed which depend on a number of confounding factors in developed nations [1,17,18]. These include the presence of a cordial relationship between the patients and their doctors, advertisement on television by law firms (73%), inability to pay medical bills (36%), and explicit recommendations from other health care providers [1,14]. A poor physician–patient relationship was implicated in about 50% of individuals who filed malpractice litigation [18]. The physician's failure to stay informed, to refer when needed, and to be available when needed were common concerns of the potential plaintiffs [17,18]. The bureaucracy of the judiciary system in Nigeria may also influence decisions to file for litigation, as there is unnecessary delay and prolongation of court proceedings. This is best illustrated by the adage "justice delayed, is justice denied."

The shortcoming in our study includes the lack of specific protocol on the maximum number of attempts at needle insertion before a senior help can be implored. The performance of the different type of neuraxial block is not restricted to a peculiar cadre of the anesthetist. However, epidural anesthesia is only performed by residents with two to two and half years

of training after proficiency in spinal anesthesia, because the former is presumed to be technically difficult. There was an acute shortage of preservative free fentanyl in our institution during the study, which prevented its administration in some subjects.

Anesthetists in Nigeria should bear in mind that patients who sustain serious injury as a result of a procedure are likely to institute a legal proceeding. In order to defend a suit, anesthetists must not breach the standard of care during such procedures. They can protect themselves by always documenting perioperative events, preexisting clinical conditions, discussion during consent, details of intraoperative anesthetic techniques and monitoring. The patients should be informed of well recognized complications following central neuraxial anesthesia. There must be detailed documentation of complications and treatment when such arises, as it may be many years after the clinical event that the anesthetist will be called upon to defend his care, long after the procedure itself is forgotten. There is therefore the need for institutions, and the national anesthesia society to improve on morbidity and mortality meetings, imbibe the use of electronic medical records, set up administrative and error monitoring committees, that will improve the database for future researches, and improve health care delivery. These reviews have illustrated that proper documentation and research are paramount in the practice of anesthesia, as they unveil complications arising in the perioperative period, thereby encouraging the practice of safe anesthesia.

5. Conclusion

Litigable complications following central neuraxial anesthesia are not a rare occurrence in our institution, however, there were no legal proceeding in the court, or with the Nigeria Medical and Dental Council. Anesthetists in Nigeria need to be aware of the possibility of a legal proceeding instituted by the patient. When such complications do occur, there is a need for proper documentation, and prompt intervention to prevent avoidable morbidity and mortality.

Conflict of interest

None declared.

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