Trends in medical disputes involving anesthesia during July 2009–June 2018: an analysis of the Korean Society of Anesthesiologists database

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Background: To identify trends in injuries and substandard care associated with anesthesia, we analyzed the Korean Society of Anesthesiologists database for anesthesia-related case files from July 2009 to June 2018.

Methods: Case characteristics, injuries, and outcomes were compared between the first part (July 2009–June 2014, n = 105) and the second part (July 2014–June 2018, n = 92) of the analyzed time period.

Results: Overall, 132 cases resulted in death. The proportion of fatal cases for sedation was similar to general anesthesia (66.2% vs. 76.3%). The proportion of cases with permanent injury or death decreased significantly in the second part of the period compared with the first part (76.1% vs. 93.3%, P = 0.002). With a growing trend in the proportion of sedation cases, a similar number of sedation and general anesthesia cases were referred during the overall period (77 and 76 cases, respectively). Propofol-based regimens remained the dominant sedation method (89.7% in the first part vs. 78.9% in the second part). The most common adverse event in cases of permanent injury or death was identified as being respiratory in origin (98/182, 53.8%). Permanent injuries or deaths were related to local anesthetic systemic toxicity (LAST) and beach-chair positioning for shoulder surgery, in 8 and 5 cases, respectively.

Conclusions: Despite the decreasing trend in injury severity with time, several characteristic injury profiles were identified: lack of vigilance in propofol-based sedation, neurological injuries related to the beach-chair position, and LAST occurring during tumescent anesthesia or brachial plexus block.

Keywords: Adverse effects; Injuries; Legislation; Malpractice.

Introduction

Following a recent increase in public expectations of the health care system and awareness of patient rights, the number of malpractice litigations in South Korea has increased [1]. As anesthesia is more likely to be associated with malpractice claims than other procedures [2], the Korean Society of Anesthesiologists (KSA) has constructed a database, based on expert consultation referrals of anesthesia-related issues since July 2009. Using these data, the KSA Legislation Committee produced several analytical papers [3–5], one of which [3] led to a great deal of public interest in anesthesia safety; in particular, the safety of propofol sedation.

Along with changes in the social environment, there have been substantial changes in the health care system during recent years, such as designation of propofol as a controlled substance, creation of the Korean guidelines for propofol-based sedation, the introduction of fees for 'monitored anesthesia care' and 'recovery after general anesthesia' in the national insurance program, and governmental regulation of operation rooms in local clinics. As a follow-up to the previous report [3], we decided to investigate trends in medical disputes relating to surgical anesthesia during recent years.

 While most medicolegal studies have used closed claims data for analysis, our data was obtained from expert consultation referrals for unsettled medical disputes. Considering the time delay between occurrence of an injury and its appearance in the closed claims database (an estimated 5–6 years for Supreme Court decisions in South Korea), the KSA database allows for analysis of more recent cases. In addition, the KSA database encompasses more diverse case files than do closed claim files because medical disputes do not necessarily lead to medical litigation.

In this report, an analysis of the KSA database covering case files for surgical anesthesia from July 2009 to June 2018 was performed to identify trends in injury and substandard care associated with anesthesia. Comparative analysis of the case files submitted during the first part (July 2009–June 2014) and those submitted during the second part (July 2014–June 2018) of the study period was also carried out.

Materials and Methods

This study is a retrospective analysis of all the case files regarding surgical anesthesia collected by the KSA between July 2009 and June 2018. Since July 2009, the KSA Legislation Committee has constructed a web-based database for evaluating adverse anesthetic outcomes obtained from the case files of expert consultation referrals. A detailed description of the data collection process has been reported previously [3,4].

During the study period, 410 cases were referred to our committee for expert consultation (police departments, 153 cases; courts, 249 cases; others [e.g., other administrative agencies or referred directly from members of the Korean Medical Association], 8 cases). Of these, simple academic consultation cases with inadequate detail, and cases unrelated to surgical anesthesia (i.e., those from pain clinics) were excluded. Because of repeated consultation requests, 58 further cases were excluded, giving a total of 197 cases eligible for the final analysis (Fig. 1). For analysis purposes, the study period was divided into 2 subperiods: July 2009–June 2014 and July 2014–June 2018.

Patient and case characteristics, adverse outcomes, and the role of substandard care in outcomes were compared between the 2 time periods. Adverse outcomes were classified as 'adverse events' or 'complications'.

An 'adverse event' refers to the primary mechanism causing injury and a 'complication' is the injury itself [6]. Adverse events were classified into broad categories based on the physiologic system or anesthesia technique implicated in the injury: respiratory events, cardiovascular events, nervous system events, allergic or adverse drug reactions, drug administration errors (wrong drug or dose), equipment problems, hepatic or renal events, endocrine events, thermal events, infectious events, and others. The nature of the adverse event was determined by the primary
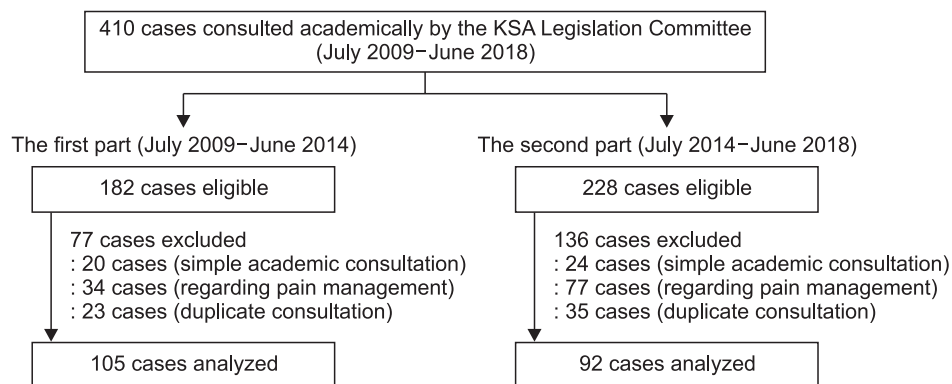

Fig. 1. Flow diagram for case selection. KSA: Korean Society of Anesthesiologists.

reviewer and later confirmed by the Legislation Committee. For further analyses, the 11 categories of adverse event were subcategorized according to specific causative mechanisms, most of which are self-explanatory.

Complications were classified into 4 categories: temporary, permanent/minor, permanent/major, and death. Severe brain damage, quadriplegia, or paraplegia requiring lifelong care or having a fatal prognosis were considered to be 'permanent/major' injuries; other permanent injuries were considered to be 'permanent/minor'.

In each case, the appropriateness of anesthesia care was rated by the primary reviewer using a 9-point numerical rating scale (NRS). This scale was designed by combining the 9-point NRS and a 3-category preventability scale (avoidable; NRS 1–3, possibly avoidable; NRS 4–6, probably unavoidable; NRS 7–9), which is known to have acceptable inter-rater reliability [7].

Statistical analysis

Categorical variables (case characteristics, injuries, and outcomes) were compared between the 2 time periods using Pearson's χ^2-test with a continuity correction or Fisher's exact test, as appropriate. Continuous variables were tested for normality using the Kolmogorov–Smirnov test. Normally distributed variables were analyzed using the unpaired t-test, while non-normally distributed continuous variables and ordinal variables were analyzed using the Mann–Whitney U test. SPSS ver. 18.0 (SPSS Inc., USA) was used for the statistical analysis. Statistical significance was set at $P < 0.05$.

Results

Of 197 cases included in the final analysis, 105 were referred in the first part of the study period (July 2009–June 2014) and 92 were referred in the second part (July 2014–June 2018).

Overall, 132 cases resulted in death. The proportion of fatal cases for sedation was similar to that for general anesthesia (66.2% [51/77] vs. 76.3% [58/76], respectively; $P = 0.169$). Sedation was the most common anesthetic technique among all cases (39.1%). However, cases involving general anesthesia were similarly prevalent, accounting for 38.6% of all cases.

Orthopedics was the most frequently involved in both time periods, followed by plastic surgery. Analysis of both time periods together showed that most patients were classified as American Society of Anesthesiologists physical status I or II (179/197, 90.9%) (Table 1).

Table 1. Comparison of Case Characteristics, Injuries, and Outcomes between the First Part (July 2009–June 2014) and Second Part (July 2014–June 2018) of the Study Period

	2009–2014 (n = 105)	2014–2018 (n = 92)	P value
Age (yr)	43.0 (26.5–55.5)	50.5 (33.3–63.5)	0.006*
Gender (F/M)	53/52	57/35	0.140
ASA physical status (I/II/III or VI)	63/32/10	53/31/8	0.885
Hospital type (local clinic/local hospital/general or academic hospital)	46/32/27	45/28/19	0.665
Type of procedure (diagnostic/cosmetic/therapeutic)	11/27/67	7/27/58	0.711
Clinical specialty (OS/PS/GS/IM/OB&GY/others)	24/18/18/10/9/26	36/20/7/12/5/12	0.023*
Type of anesthesia (GA/sedation/SP/ED/PNB/LA)	50/39/7/4/2/3	26/38/12/9/5/2	0.036*
Timing of adverse events (induction/maintenance/recovery/at ward/discharge)	23/34/19/25/4	8/47/21/13/3	0.014*
Complications[†] (temporary/permanent [minor]/permanent [major]/death)	3/4/16/82	12/10/20/50	0.002*
Appropriateness of anesthetic care[†] (avoidable/possibly avoidable /probably unavoidable)	45/31/29	31/30/31	0.404

Values are expressed as numbers of cases or medians (interquartile range). ASA: American Society of Anesthesiologists, OS: orthopedic surgery, PS: plastic surgery, GS: general surgery, IM: internal medicine, OB&GY: obstetrics and gynecology, GA: general anesthesia, SP: spinal anesthesia, ED: epidural anesthesia, PNB: peripheral nerve block, LA: local anesthesia. *Statistically significant at $P < 0.05$. Categorical variables: Pearson's χ^2-test with a continuity correction or Fisher's exact test, continuous variables: unpaired t-test or Mann–Whitney U test. [†]Complications were classified into 4 categories: temporary, permanent/minor, permanent/major, and death. 'Permanent/major' injuries included severe brain damage, quadriplegia, and paraplegia requiring lifelong care or having a fatal prognosis; other permanent injuries were considered to be 'permanent/minor'. [‡]Appropriateness of anesthesia care was graded on a 1–9 point scale (1 = completely avoidable injury, 9 = completely unavoidable injury, if an appropriate standard of care had been used). Then, they were classified into a 3-category preventability scale (1–3, avoidable; 4–6, possibly avoidable; 7–9, probably unavoidable).

Comparison of case characteristics between the 2 time periods

The proportion of cases with permanent injury or death decreased significantly in the second half of the study period compared with the first half (76.1% vs. 93.3%, P = 0.002). The distribution of anesthesia types was significantly different between the 2 time periods (P = 0.036), with an increasing trend in the proportion of sedation cases over time (37.1% in the first part vs. 41.3% in the second part) (Table 1).

Injuries arising from the induction phase of anesthesia decreased in the second part compared with the first part (8.7% [23/105] vs. 21.9% [8/92]) (Table 1). Among sedation cases, only 1 case was associated with induction of anesthesia in the second part, compared with 6 cases in the first part (Table 2).

In 76 cases (38.6% of all cases), the injuries were determined to be 'avoidable (1–3 in a 9-point NRS)' if an appropriate standard of care had been used (Table 1). The appropriateness of anesthesia care, graded using a 9-point NRS, was not different between the 2 time periods (medians [interquartile range]: 4.0 [2.0–7.0] in the first part vs. 5.0 [3.0–8.0] in the second part, P = 0.162).

Analysis of sedation cases

The safety measures for sedation did not change significantly between the first and second parts of the study period, as evidenced by pre-anesthetic testing (no test: 82.1% vs. 71.1%), intraoperative monitoring (absence of pulse oximetry: 15.4% vs. 18.4%), and administration of supplemental oxygen (without oxygen: 61.5% vs. 78.9%) (Table 2). However, the proportion of injuries arising from the induction phase decreased in the second part of the study period (2.6%, 1/38) compared with the first part (15.4%, 6/39) (Table 2).

Propofol-based regimens remained as the dominant sedation method among all sedation cases (89.7% [35/39] in the first part vs. 78.9% [30/38] in the second part). Death occurred in 69.2% (45/65) of all cases involving propofol-based sedation, with a similar mortality between the 2 time periods (P = 0.195) (Fig. 2). Propofol-based sedation was usually provided simultaneously with the surgical/diagnostic procedure by the non-anesthesiologists who performed the operation (85.7% in the first part vs. 93.3% in the second part).
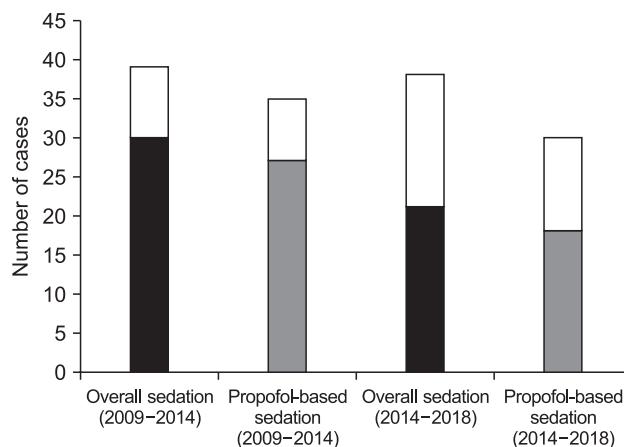

Fig. 2. Comparison of mortality in overall sedation and propofol-based sedation cases between the 2 time periods (July 2009–June 2014 vs. July 2014–June 2018). Black or gray color represents fatal cases.

Table 2. Comparison of General Anesthesia and Sedation Cases between the First Part (July 2009–June 2014) and Second Part (July 2014–June 2018) of the Study Period

	GA (n = 76)		Sedation (n = 77)	
	2009–2014	2014–2018	2009–2014	2014–2018
Timing of adverse events (induction/maintenance/after procedures)	13/7/30	3/5/18	6/21/12	1/31/6
Pre-anesthetic test (absent/present)	1/49	0/26	32/7	27/11
Pre-anesthetic evaluation record (absent/present)	23/27	16/10	36/3	35/3
Anesthesia record (absent/present)	0/50	0/26	35/4	29/9
Grade of intraoperative monitoring* (grade I/II/III/IV)	0/0/25/25	0/1/15/10	6/21/11/1	7/22/9/0
Supplemental oxygen (no/yes)	0/50	0/26	24/15	30/8
Anesthesia or sedation provider (nurse/anesthesiologist/other doctors)	1/49/0	1/25/0	0/3/36	0/2/36
Permanent (minor/major)/death	1/7/42	3/7/16	0/6/30	3/11/21
Appropriateness of anesthesia care[†] (avoidable/possibly avoidable/probably unavoidable)	13/19/18	3/7/16	27/7/5	21/15/2

Values are presented as numbers of cases. GA: general anesthesia. *Intraoperative monitoring: grade I, no monitoring; grade II, pulse oximetry only; grade III, grade II plus non-invasive blood pressure measurement and/or electrocardiography; grade IV, grade III plus capnography. [†]Appropriateness of anesthetic care was graded on a 1–9 point scale (1 = completely avoidable injury, 9 = completely unavoidable injury, if an appropriate standard of care had been used). Then, they were classified into a 3-category preventability scale (1–3, avoidable; 4–6, possibly avoidable; 7–9, probably unavoidable).

Table 3. Comparison of Adverse Events Associated with Permanent Injury or Death between the First Part (July 2009–June 2014) and Second Part (July 2015–June 2018) of the Study Period

	2009–2014 (n = 102)	2014–2018 (n = 80)
Respiratory adverse events	56	42
Difficult intubation	8	3
Premature extubation	3	2
Airway obstruction or respiratory Depression	31	36
Aspiration	5	0
Bronchospasm	5	1
Pneumo-or hydrothorax	2	0
Pulmonary edema	2	0
Cardiovascular adverse events	26	17
Myocardial infarction	12	6
Pulmonary embolism	7	3
Hypovolemia due to massive bleeding	3	2
Critical arrhythmia	2	3
Unexplained cardiac arrest	2	3
Nervous adverse events	9	11
Central/peripheral	6/3	5/6
Allergic or adverse drug reactions	5	8
Local anesthetic systemic toxicity	3	5
Anaphylactic reaction	2	1
Wrong drug or dose	0	2
Hepatic or renal events	1	0
Hepatic failure	1	0
Endocrine events	1	0
Hypoglycemia	1	0
Thermal events	2	1
Hypothermia/malignant hyperthermia	1/1	0/1
Infectious events	2	1
Sepsis	2	1

Values are presented as numbers of cases.

Adverse events in cases with permanent injury or death during the overall study period

Table 3 lists the adverse events in cases of permanent (minor or major) injury or death. Among these, the most common adverse events were respiratory in nature (98/182, 53.8%). The most common type of respiratory issues was 'hypoxia secondary to airway obstruction or respiratory depression' in both time periods. The second part of the period showed a decreasing trend for difficult intubation, aspiration, and bronchospasm compared with the first part (3, 0, and 1 vs. 8, 5, 5 cases, respectively).

Although cardiovascular events were the second most common adverse events throughout the study period, the 2 subclasses of cardiovascular events (acute myocardial infarction and pulmonary embolism) showed a declining trend in cases with permanent injury or death.

Notably, there was a growing trend toward local anesthetic systemic toxicity (LAST) cases, which accounted for 4.4% of the

events leading to permanent injury or death. Of these, 5 cases were related to tumescent anesthesia for liposuction (n = 3) and osmidrosis (n = 2). The others occurred during brachial plexus block (n = 3).

There were 5 cases of permanent injury or death in patients undergoing shoulder surgery in the beach-chair position. Among these, there were 2 cases of death or vegetative state due to cerebral infarction, and 1 of death due to acute myocardial infarction. In 2 other cases, death was unrelated to patient position. Rather, the cause of death was identified as LAST during brachial plexus block performed under general anesthesia and failed airway management after premature extubation, respectively.

Discussion

Both the medicolegal environment and governmental policy pertaining to the health care system significantly influence trends in clinical practice. Our analysis of contemporary cases of medical disputes will enable practitioners to improve their understanding of recent trends in anesthesia-related injuries and thus deliver targeted interventions in specific cases susceptible to litigation.

Changes in severity and types of injury throughout the 2 time periods

The most positive finding of our analysis was the decrease in the proportion of cases resulting in death or permanent/major injury, from 93.3% in the first part of the study period to 76.1% in the second part. This may reflect the overall improvement in anesthesia practice, although our analysis included a small sample size. Another possibility is that patients and their families became more inclined to sue for less serious anesthesia-related injuries.

In the analysis, the second part of the study period showed a decreasing trend in cases of difficult intubation, aspiration, and bronchospasm compared with the first part. This decrease in fatal respiratory adverse events may also have led to the reduced severity of injuries in the second part of the study period.

Although the proportion of cardiovascular events in cases with permanent injury or death was similar between the 2 time periods, our analysis showed a decreasing trend in cases attributable to acute myocardial infarction. In South Korea, the incidence of overall coronary heart disease has consistently increased due to westernization of the diet, changes in lifestyle, and aging of the population. However, the incidence of hospitalized acute myocardial infarction has shown a decreasing tendency [8]. In this regard, a decreasing trend for acute myocardial infarction cases may be attributable to improved preoperative

management, including preanesthetic evaluation.

Lack of improvement in 'patient safety' in sedation

During the overall study period, an almost equal number of sedation and general anesthesia cases were referred to the KSA for academic consultation regarding medical disputes (77 and 76 cases, respectively). Compared to the first part of the period (July 2009–June 2014), the second part (July 2014–June 2018) showed a higher proportion of sedation cases. In addition to the increase in number, sedation cases showed a high proportion of patient injuries, similar to those seen in general anesthesia cases (overall mortality: 66.2% vs. 76.3%, respectively).

In particular, 84.4% of all sedation cases involved propofol-based regimens, and this high proportion did not differ between the 2 time periods. This finding might be partially related to an increase in the number of the denominator (overall propofol-based sedation), especially in diagnostic gastrointestinal endoscopy and esthetic surgery [9,10]. The analysis demonstrated that safety measures for propofol-based sedation were similar throughout the study period in terms of preanesthetic evaluation, intraoperative monitoring, supplemental oxygen therapy, and documentation. In particular, 64.6% of the injuries related to propofol-based sedation were considered preventable with better monitoring or more timely management for adverse events.

Considering that the proportion of injuries arising from the induction phase decreased in the second part of the study period (2.6%, 1/38) compared with the first part (15.4%, 6/39), it is likely that practitioners grew more cautious regarding the potential cardio-respiratory risks of sedative drugs including propofol during this phase. However, this vigilance did not extend to the maintenance phase of sedation. Among propofol-based sedation cases, sedation was typically provided simultaneously with the surgical/diagnostic procedure by non-anesthesiologists who performed the operation (85.7% in the first part of the study period and 93.3% in the second part). Most practitioners, especially in the context of a surgical/diagnostic procedure, are prone to concentrate on the surgical field or endoscopy monitor rather than the patient's respiration. Such a phenomenon, known as 'inattentional blindness', was best evidenced by the famous "invisible gorilla" psychological experiment [11].

In addition, detection of apnea or hypoventilation may be delayed by using a pulse oximeter only [12]. Thus, the KSA guidelines strongly advocate an additional health professional solely for patient monitoring throughout propofol-based sedation [13]. As most propofol-based sedation cases are for simple or superficial operations that are performed in relatively healthy patients, strict adherence to practical guidelines may improve patient safety significantly.

Safety issues regarding the beach-chair position for shoulder surgery

As reported above, there were 5 cases of permanent injury or death in patients undergoing shoulder surgery in the beach-chair position. Of these, there were 2 cases of death or vegetative state due to cerebral infarction, and 1 death due to acute myocardial infarction. In the remaining cases, death was unrelated to patient position.

The beach-chair position is commonly used for both arthroscopic and open shoulder surgeries because of the ease of transition from a supine to an upright position, excellent intra-articular visualization, reduced bleeding, and a lower incidence of traction neuropathy. However, the beach-chair position can cause significant neurologic complications, ranging from cranial nerve injury to infarction, which are hypothesized to occur secondary to cerebral hypoperfusion [14]. In addition, incorrect head and neck positioning in the beach-chair position can reduce vertebral artery blood flow or impede cerebral venous drainage, resulting in mid-cervical quadriplegia or cerebral infarct [14].

Another notable complication unique to the beach-chair position is sudden, profound hypotension and bradycardia events (HBEs). Although HBEs (a form of vasovagal syncope mediated by the Bezold–Jarisch reflex), are largely self-limiting, they can lead to potentially catastrophic complications [14,15]. In particular, a combination of the beach-chair position and brachial plexus block is known to precipitate frequent and severe vasovagal episodes [16]. Although in this analysis, adverse events of 2 cases were classified as LAST and acute myocardial infarction, precipitation of HBEs could not be ruled out. This is because, brachial plexus blocks were used in those cases. Thus, practitioners must be cognizant of the complications unique to the beach-chair position and should take extra care, including preoperative identification of patients at high risk for cerebral ischemia (e.g., those with diabetes, autonomic neuropathy, or cerebrovascular disease), maintenance of a safe position of the head and neck during surgery, and intraoperative maintenance of cardiac output and mean arterial pressure.

LAST occurring during tumescent anesthesia or brachial plexus block

In total, 8 cases of permanent injury or death were attributed to LAST. Of these, 5 were related to tumescent anesthesia for liposuction of the abdomen (n = 2) and face (n = 1), and 2 to axillary osmidrosis. Except for 1 case resulting in a vegetative state, all cases resulted in death.

Originally developed to facilitate liposuction, the use of tumescent anesthesia has expanded to encompass various der-

matologic and plastic surgeries. Although well-tolerated, this technique is not without safety risks, given the high volume of lidocaine frequently administered. Generally, 0.01%–0.1% lidocaine with epinephrine at a total dose of 35–55 mg/kg is used in tumescent anesthesia for liposuction [17]. The maximum safe dose of tumescent lidocaine for liposuction is still uncertain because of the highly variable volumes of lidocaine removed by liposuction, and the intense local vasoconstriction associated with concurrent use of epinephrine [17,18]. Risk factors for LAST include impaired liver or renal function, use of higher concentrations of lidocaine, rapid injection, perivascular injection, and omission of epinephrine from the tumescent formulation [17]. Thus, practitioners should be vigilant regarding the signs and symptoms of LAST, prepare algorithms for its use, and ensure rescue equipment and drugs including lipid emulsion, are available.

The other form of LAST identified was inadvertent intravascular injection of local anesthetic during brachial plexus block (n = 3), in which a mixture of lidocaine and ropivacaine was used. The incidence of LAST is greater with brachial plexus block than neuroaxial blocks because larger-than-usual doses of local anesthetics are used, and injections are made in and around large vascular channels in the head, neck, and axillary regions [19].

This type of adverse event is preventable via basic precautions during administration of local anesthetic: selecting the lowest possible dose to achieve the clinical objective, injecting incrementally so that the entire dose is not administered at once; aspirating frequently; and using epinephrine to detect intravascular injection [20]. In addition, all the necessary drugs and equipment required for LAST management should be immediately at hand.

Limitation of the KSA database analysis

As stated in previous KSA reports [3–5], this study should be interpreted cautiously due to the inherent limitations of this type of analysis: being retrospective in nature, employing nonrandomized data collection, lacking denominator data, and showing a bias toward classifying care as substandard in cases with poor outcomes [2,6]. Criticism could also be leveled at the short study period for investigating trends in anesthetic practic-

es. However, as stated in the introduction section of this paper, there have been substantial changes in the health care system and social environment surrounding anesthetic practices during the study period.

In conclusion, this study demonstrated reduced severity of anesthesia-related injuries during the second part of the analysis period (July 2014–June 2018) compared with the first (July 2009–June 2014). Compared with the first part, the proportion of sedation cases increased in the second part, such that there was a similar number of sedation and general anesthesia cases in both periods.

Our analysis also revealed several 'typical' injury profiles: a lack of safety measures for propofol-based sedation, neurological injuries related to use of the beach-chair position for shoulder surgery, and LAST occurring during tumescent anesthesia or brachial plexus block. Thus, greater emphasis on patient safety is necessary in these clinical situations.

Conflicts of Interest

Author Contributions

Ji Won Choi (Formal analysis; Methodology; Validation; Visualization)
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Choon Kyu Cho (Validation; Writing – review & editing)
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