

Comparative Analysis of Anesthetic Legal Disputes between Older and Younger Patients Referred to the Korean Society of Anesthesiologists in 2009–2018

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Received: July 8, 2019 Revised: September 25, 2019 Accepted: November 29, 2019 Background: Although the average age of patients undergoing surgical procedures or anesthesia is increasing, differences in anesthesia-related injuries among different age groups have been not reported. This study compared older and younger patients on the basis of disputes regarding anesthesia-related injuries referred to the Korean Society of Anesthesiologists (KSA). Methods: We retrospectively analyzed disputes regarding anesthesia-related injuries referred to the KSA between 2009 and 2018. After excluding duplicates, incomplete data, local anesthesia cases, and patients aged ≤ 18 or 55–64 years, the subjects were divided into older (≥ 65 years) and younger (19-54 years) age groups. The parameters included in the KSA database were compared between these two groups. Results: The 115 cases included in the study included 28 and 87 cases from the older and younger groups, respectively. The proportions of preventable cases of anesthesia-related adverse events differed significantly between the older (25%) and younger groups (48.3%). The most common medical disputes in the older group were related to general anesthesia, orthopedic surgery, local hospitals, and anesthesiologist, whereas those in the younger group were related to sedation, plastic surgery, local clinics, and non-anesthesiologists. Conclusion: In addition to understanding the differences in anesthesia characteristics according to age group, it is also necessary to develop means for reducing preventable anesthesia-related adverse events. Furthermore, we must continue to register anesthesia-related disputes, and a voluntary reporting system should be established to prevent anesthesia-related accidents.

Key Words: Anesthesia, Geriatric assessment, Dissent and disputes

INTRODUCTION

South Korea became an aged society in August 2017. With 14.3% of the population considered aged in July 2018, it will become a post-aged society by 2026 according to the Korean Statistical Information Service.¹⁾ According to the Health Insurance Review and Assessment Service (HIRA), the rate of geriatric anesthesia (age ≥ 65 years) has been increasing, accounting for 26% of all cases of anesthesia in 2018 and exceeding the proportion of aged people in the population. Furthermore, age is a risk factor for anesthesia and surgery. Therefore, it is important to closely monitor geriat-

ric anesthesia and related injuries.

Injuries require treatment and patients make claims when unexpected damage occurs. As injuries related to anesthesia can cause serious patient injury, opinions and feedback from various sources are needed to solve this problem. Since the American Society of Anesthesiologists (ASA) organized the Closed Claim Project in 1985, research on patient safety has been conducted continuously, and patient safety concerning anesthesia has improved. The Korean Society of Anesthesiologists (KSA) established a database in 2009 at the request of the courts, public prosecutor's office, and police regarding medical disputes or claims for problems associat-

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ed with anesthesia. The findings of several analytical studies based on the KSA database²⁻⁴⁾ have led to changes in healthcare policies. However, to our knowledge, no comparative studies have used this database to assess anesthesia-related injuries according to age group. Therefore, the present study compared older and younger patients on the basis of medical disputes referred to the KSA between 2009 and 2018.

MATERIALS AND METHODS

Study Design and Population

The present study was approved by the Institutional Review Board of Konyang University Hospital (No. KYUH-2018-06-017). We retrospectively analyzed the database, which was developed by the KSA in 2009–2018. There was no requirement to obtain informed consent from the subjects because of the retrospective nature of the study.

The inclusion criteria were legal claims associated with anesthesia in cases referred to the KSA in 2009–2018. Of those, duplicate cases because of re-consultation, cases in which a connection between anesthesia and outcome could not be confirmed because of incomplete data, cases involving local anesthesia, and cases in which the patients were aged ≤ 18 or 55–64 years were excluded. The parameters registered in the KSA database were compared between the remaining subjects, who were divided into older (≥ 65 years) and younger (19–54 years) age groups.

Patients Characteristics

The patients' characteristics included age, sex, ASA physical status classification, pre-anesthetic assessment, and surgical diagnosis. The characteristics of the surgery included its nature (cosmetic, disease treatment, or diagnosis), types (plastic surgery, orthopedic surgery, general surgery, obstetrics and gynecology, urology, oto-laryngology, ophthalmology, neurosurgery, cardiothoracic surgery, dental, or 'non-surgery'—i.e., procedures performed by non-surgeons, such as general physicians, internal medicine physicians, family medicine physicians, dermatologists, and anesthesiologists), and the types of hospital in which the operation took place (university or general hospital, local hospital, or local clinic). The characteristics of anesthesia included the types of anesthesia (general, spinal, epidural, sedation—defined here as only procedural sedation—or peripheral nerve block), anesthesia provider (anesthesi-ologist, non-anesthesiologist, or nurse), and induction agent.

Outcome assessments

Adverse events, defined as the cause of the final outcome, were classified as respiratory system, cardiovascular system, nervous system, or other events (musculoskeletal-system, skin, hepatic or renal, endocrine, thermal, or infectious events; transfusion reactions; equipment problems; incorrect drug or dose; drug reactions; and others). The outcomes were defined by the final result of the adverse event and were classified as temporary, permanent, or death. Permanent injury was defined as cases requiring continuous treatment, such as brain damage, quadriplegia, or irreversible neurological damage. The appropriateness of anesthesia was assessed by a reviewer who provided an expert consultation about the assigned cases using a numeric rating scale (NRS) from 1 to 9, in which 1 was the least appropriate and 9 was most appropriate in the process of anesthesia. On the basis of appropriateness, we estimated the preventability of the adverse event or outcome,⁴⁾ which was the possibility that a certain injury could have been prevented by appropriate treatment or precautions. NRS 1-3 included preventable events, that is, events that could easily have been prevented; NRS 4-6 included moderately preventable events, that is, events that might have been preventable; and NRS 7-9 included hardly preventable events, that is, events that were unlikely to have been prevented.⁴⁾ The primary outcome was the percentage of preventable events. In addition, in the older patient group, we determined whether a preoperative frailty evaluation or comprehensive geriatric assessment had been carried out.

We performed comparisons between total cases and cases without sedation because sedation is used mainly in cosmetic or diagnostic procedures, which are expected to differ from other procedures in terms of patient age distribution. Moreover, the causes of accidents in sedated patients were different from those in other patients administered anesthesia.⁵⁻⁸⁾

Statistical Analyses

Statistical analyses were carried out using PASW Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA). The patients' characteristics, surgical characteristics, anesthesia characteristics, adverse events, outcomes, and appropriateness were compared between the older and younger groups. Continuous data were analyzed using Student t-test or Mann– Whitney U-test depending on the variables and normality, whereas categorical data were analyzed using the chi-square test or Fisher exact test. p-values < 0.05 were considered statistically significant.

RESULTS

Anesthesia-related claims in 154 cases in the target age groups were referred to the KSA; of these, 115 cases were analyzed after excluding duplicate cases, cases of incomplete data, and local anesthesia cases. A flowchart is shown in Fig. 1.

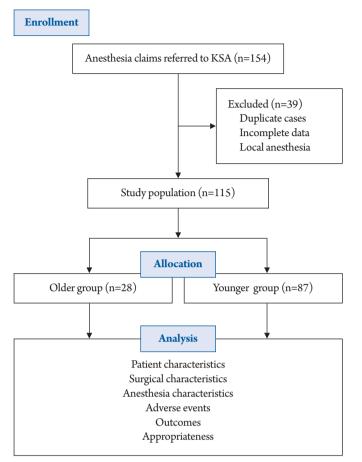


Fig. 1. Study flowchart. KSA, Korean Society of Anesthesiologists.

Comparisons of the Older and Younger Groups: Analysis of Total Cases

The older and younger groups included 28 and 87 cases, respectively. The differences between the two groups are presented in Table 1. The percentages of preventable cases were 25% in the older group and 48.3% in the younger group (p = 0.047). The distributions of ASA physical status classification differed significantly between the two groups (p = 0.003), with 75% ASA class-I and -II cases in the older group and 90.8% in the younger group. The types of anesthesia also differed significantly between the two groups (p < 0.001), with general anesthesia most common in the older group and sedation most common in the younger group (50.0% and 52.9%, respectively). The nature of the surgery also differed significantly between the two groups (p < 0.001), although treatment was the most common reason for surgery in both (89.3% and 48.3%, respectively). The distribution of hospital type in which anesthesia differed significantly between the two groups (p < 0.001); with local hospitals most common in the older group and local clinics in the younger group (53.6% and 59.8%, re-

	Older (n=28)	Younger $(n=87)$	p-value
Age (y)	74 (70–80.8)	37 (28–46)	< 0.001
Sex, male	14 (50.0)	32 (36.8)	0.269
ASA class			0.003
Ι	3 (10.7)	60 (69.0)	
II	18 (64.3)	19 (21.8)	
III	7 (25.0)	3 (3.5)	
NE	0 (0)	5 (5.7)	
Types of anesthesia			< 0.001
General	14 (50.0)	30 (34.5)	
Spinal	7 (25.0)	5 (5.7)	
Epidural	3 (10.7)	3 (3.4)	
Sedation	4 (14.3)	46 (52.9)	
Peripheral nerve block	0(0)	3 (3.4)	
Nature of surgery			< 0.001
Cosmetic	0(0)	38 (43.7)	
Treatment	25 (89.3)	42 (48.3)	
Diagnosis	3 (10.7)	6 (6.9)	
Other	0(0)	1(1.1)	
Types of hospital			< 0.001
University or general hospital	11 (39.3)	13 (14.9)	
Local hospital	15 (53.6)	22 (25.3)	
Local clinic	2 (7.1)	52 (59.8)	
Anesthesia provider			< 0.001
Anesthesiologist	23 (82.1)	38 (43.7)	
Non-anesthesiologist	5 (17.9)	46 (52.9)	
Nurse	0(0)	3 (3.4)	
Anesthesia consent	16 (57.1)	44 (50.6)	0.665
Presence of anesthesia records	23 (82.1)	46 (52.9)	0.007
Full-time anesthesiologist	23 (82.1)	37 (42.5)	< 0.001
Preventable case	7 (25.0)	42 (48.3)	0.047
Outcomes			0.152
Death	23 (82.1)	59 (67.8)	
Permanent injury	3 (10.7)	24 (27.6)	
Temporary injury	2 (7.1)	4 (4.6)	

Table 1. Comparisons of the older and the younger groups: total cases

Values are expressed as the median (Q1–Q3) or number (%).

ASA, American Society of Anesthesiologists; NE, not evaluated.

spectively). The distributions of anesthesia providers also differed significantly between the two groups (p < 0.001), with anesthesiologists the most common provider in the older group and non-anesthesiologists most common in the younger group (82.1% and 52.9%, respectively). The presence of anesthesia records was significantly higher in the older group than in the younger group (82.1% and 52.9% of cases, respectively; p = 0.007). The percentage of hospitals directly employing anesthesiologists was also significantly higher in the older group than that in the younger group (82.1% and 42.5%, respectively; p < 0.001). The mortality rates

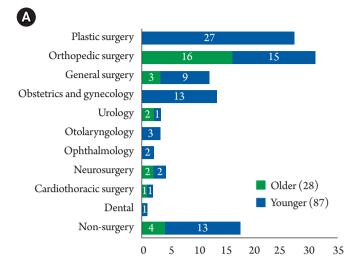
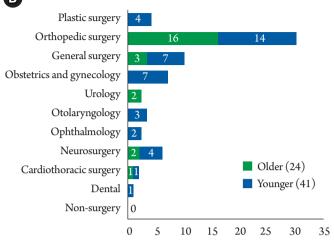


Fig. 2. Type of surgery: (a) total cases and (b) cases without sedation.

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were 82.1% in the older group and 67.8% in the younger group.

Fig. 2A presents the types of surgery in the two groups. Orthopedic surgery was the most common type in the older group, whereas plastic surgery was the most common type in the younger group (57.1% and 31%, respectively).

Adverse events are presented in Fig. 3A. The most common adverse events were cardiovascular system events in the older group and respiratory system events in the younger group (57.1% and 50.6%, respectively; p = 0.009). No patients with the older group had received preoperative frailty evaluations or comprehensive geriatric assessments.

Comparisons of Older and Younger Groups without Sedation

The 65 patients who were not sedated included 24 and 41 patients in the older and younger groups, respectively. Table 2 shows the comparisons of the two age groups without sedation. The percentages of preventable cases were 16.7% in the older group and 29.3% in the younger group, which were lower than those observed in the total case analysis. The distribution of ASA physical status classifications differed significantly between the two groups (p < 0.001), with 75% and 92.7% of cases categorized as ASA class-I and -II in the older and younger groups, respectively. The distributions of hospital types differed significantly between the older and younger groups (p = 0.027), with local hospitals being the most common in both groups (54.2% and 48.8%, respectively). General anesthesia was the most common in both groups, at 58.3% and 73.2% among those without sedation, respectively. The most common anesthesia providers were anesthesiologists in both groups without sedation (95.8% and 82.9%, respectively). The mortality rates did not differ significantly between the older and younger groups,

at 79.2% and 75.6%, respectively, after excluding patients with sedation.

Orthopedic surgery was most common in both the older and younger groups (76.2% and 34.1%, respectively) (Fig. 2B) regardless of sedation. Cardiovascular events were the most common adverse events in both groups (66.7% and 39%, respectively) among those without sedation (Fig. 3B).

DISCUSSION

We observed a difference in legal anesthesia-related disputes between older and younger groups and propose that an increased understanding of the factors leading to the differences between the two groups might help prevent anesthesia-related accidents.

Although cardiovascular and respiratory events were overall the most common adverse events in the older group younger groups, cardiovascular events were the most common in both groups without sedation. This difference may have been due to differences in the types of surgery and anesthesia between the older and younger groups. Only 3% of cases had monitored anesthesia care (MAC) in a study of closed claims in 2012,⁵⁾ and MAC claims were associated with higher age, higher ASA, and similar percentages of death and brain damage compared with other anesthesia-related claims.⁶⁾ Furthermore, as there were no sedation-related claims in an analysis of anesthesia-related medical disputes referred to the KSA in $2004^{(7)}_{\mu}$ cosmetic procedures using propofol sedation appear to have begun to be performed mainly in younger patients. Except for sedation, although the ASA physical status was higher in older group than that in the younger group, there were no differences in the type of surgery, type of anesthesia, or preventable cases be-

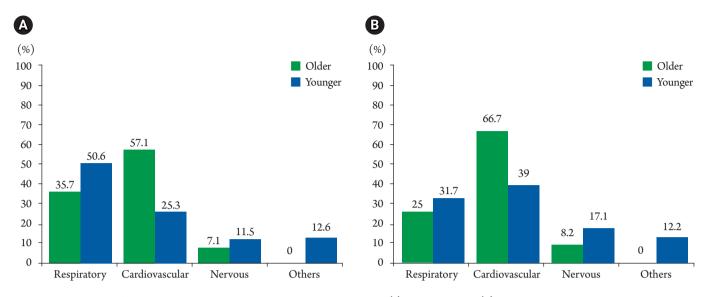


Fig. 3. Comparison of adverse events between the older and younger groups: (a) total cases and (b) cases without sedation. 'Others' includes musculoskeletal-system, skin, hepatic or renal, endocrine, thermal, or infectious events; transfusion reactions; equipment problems; inappropriate drug or dose; drug reaction, etc.

tween the two groups. The percentages of patients with sedation and of younger age in this study were higher than those reported in a closed claims study in the United States (US);⁸⁾ these factors may have contributed to the difference in preventable events between the two groups.

We expected that claims would be rare in older patients, as we assumed that death or injury would be more readily accepted in these patients, even in the context of critical events. As older adults often have multiple comorbidities, such as diabetes mellitus, hypertension, and cardiac hypertrophy, they are not only a high-risk group for anesthesia and surgery but also require management in terms of baseline diseases.^{9,10)} In addition, anesthesia in geriatric patients must be administered carefully because of their decreased sympathetic response, venous compliance, and cardiac preload; propensity for injury in association with glucose tolerance; diastolic dysfunction; and decline in renal function and mass.¹¹⁾ Indeed, the rate of claims by older patients is about 5-10 times lower than that by younger patients.¹²⁾ In addition, as our older patients received appropriate explanations and provided consent on the basis of their family's understanding of their condition and the associated risks in the event of problems, we expected a low likelihood of medical disputes when negative results occurred. Contrary to our expectations, however, the percentage of claims referred to the KSA in the older group was 24.3% and increased to 36.9% after excluding cases with sedation. Although older adult patients comprised 14.3% of the population in 2018,¹⁾ 26.2% of cases of anesthesia involved older adults. Thus, the percentage of older patients undergoing anesthesia for surgery is higher than the percentage of

older adults in the overall population.

Reducing the overall number of claims requires examination of the current problems associated with sedation. Our results regarding sedation-related problems are consistent with those of previous studies¹³⁻¹⁵⁾ showing that respiratory system events were the most common adverse events. Several studies^{4,13-17)} have warned of the risk of respiratory depression associated with propofol overdose. The risk of propofol overdose is emphasized because the metabolic ability varies 19-fold among individuals;¹⁸⁾ thus, a lack of sufficient physician attention is related to a high risk of overdose. A previous study using the KSA database of 2009–2014⁴⁾ showed that most cases of sedation were managed by a non-anesthesiologist (92.3%) and were associated with the use of propofol (89.7%), similar to our observations. Our results show that propofol accounted for 92% of sedation-related claims, which is a comparably high percentage to that reported previously.

The European National Societies of Anesthesia concluded that non-anesthesiologists should not use propofol as a sedative agent for clinical procedures.¹⁶⁾ Moreover, Korean studies^{4,19)} have recommended that propofol be used only with close monitoring by authorized clinicians or anesthesiologists. Despite these concerns, the use of propofol and critical problems related to its use have increased in Korea.¹⁹⁾ Furthermore, claims for sedation-related injuries continue to be made. Although sedation can be performed by any qualified specialist, simultaneous anesthesia and surgery is difficult.⁴⁾ Recently, the European Society of Anesthesiology proposed a minimal requirement that those performing procedural sedation be able to assess and manage the level sedation.²⁰⁾ They also recom-

	Older $(n=24)$	Younger $(n=41)$	p-value
Age (y)	74 (70–80.8)	42 (32–50)	< 0.001
Sex, male	12 (50.0)	22 (53.7)	0.776
ASA class			< 0.001
Ι	2 (8.3)	23 (56.1)	
II	16 (66.7)	15 (36.6)	
III	6 (25.0)	2 (4.9)	
NE	0(0)	1 (2.4)	
Types of anesthesia			0.178
General	14 (58.3)	30 (73.2)	
Spinal	7 (29.2)	5 (12.2)	
Epidural	3 (12.5)	3 (7.3)	
Peripheral nerve block	0 (0)	3 (7.3)	
Nature of surgery			0.288
Cosmetic	0(0)	4 (9.8)	
Treatment	24 (100.0)	37 (90.2)	
Types of hospital			0.027
University or general hospital	10 (41.7)	9 (22.0)	
Local hospital	13 (54.2)	20 (48.8)	
Local clinic	1 (4.2)	12 (29.3)	
Anesthesia provider			0.356
Anesthesiologist	23 (95.8)	34 (82.9)	
Non-anesthesiologist	1 (4.2)	4 (9.8)	
Nurse	0(0)	3 (7.3)	
Anesthesia consent	16 (66.7)	28 (68.3)	1.000
Presence of anesthesia records	23 (95.8)	36 (87.8)	0.400
Full-time anesthesiologist	22 (91.7)	29 (70.7)	0.063
Preventable cases	4 (16.7)	12 (29.3)	0.373
Outcome			0.647
Death	19 (79.2)	31 (75.6)	
Permanent injury	3 (12.5)	8 (19.5)	
Temporary injury	2 (8.3)	2 (4.9)	

Table 2. Comparisons of the older and the younger groups after excluding cases with sedation

Values are expressed as the median (Q1-Q3) or number (%).

ASA, American Society of Anesthesiologists; NE, not evaluated.

mended that procedural sedation and analgesia be performed in an environment in which an anesthesiologist is readily available.²⁰⁾ Several methods have been proposed to resolve the problems associated with sedation, including strengthening the sedation monitoring standards, for example, via addition of end-tidal CO_2 (EtCO₂) monitoring, making the monitoring of operations by doctors mandatory (depending on the type or difficulty of surgery), or mandating anesthesiologist participation in sedation. Such measures could help prevent sedation-related accidents. In situations requiring the use of propofol, the 'Practice Guidelines for Propofol Sedation by Non-anesthesiologists²¹⁾, should be followed.

On the basis of the numbers of cases of anesthesia investigated

by the HIRA in 2018 (1,112,139 in university and general hospitals, 689,872 in local hospitals, and 124,779 in local clinics) as well as the poor condition of patients and the difficulty in performing surgery in university or general hospitals, the number of anesthesia accidents were predicted to be higher in university or general hospitals than in other hospitals. However, local hospitals and local clinics were most commonly associated with claims in the older group and younger groups, respectively. The low rate of cases proceeding to a dispute in university or general hospitals may be due to the provision of adequate explanations about anesthesia before surgery, as well as to the provision of informed consent, the difficulty of determining whether the accident was caused by anesthesia or surgery, and physician recognition of poor patients' condition. In contrast, the increased numbers of disputes in local hospitals and local clinics may be due to the lower likelihood of adequate explanations regarding anesthesia before surgery, lower rate of informed consent, and deficiencies in physician education and ability to cope with medical disputes. Furthermore, as the behavior of physicians and their ability to communicate with patients affect the numbers of claims,²²⁾ disputes are more likely in local hospitals and local clinics characterized by a lack of communication between physicians and patients because of the absence of full-time anesthesiologists.²³⁾ In our study, the anesthesiologists were full-time in only 42.5% of hospitals in the younger group and written consent for anesthesia was obtained in only half of cases across both groups. Freelance anesthesiologists are relatively common in Korea, which may have been the cause of improper preanesthetic assessments²³⁾ and inadequate explanations about anesthesia before surgery.

However, there are other problems associated with anesthesia in Korea in addition to inadequate explanations and lack of informed consent. There were no claims involving intubation failure during the induction of general anesthesia at university or general hospitals in the KSA database, whereas four deaths related to intubation failure had occurred in local clinics and hospitals. Adequate equipment, such as videoscopes or bronchoscopes, as well as sufficient manpower to address airway problems is likely to be available in university or general hospitals. However, anesthesia providers at local hospitals or clinics are not usually available full time,²³⁾ and shortage of manpower and equipment is possible. Freelance anesthesiologists may not be sufficiently familiar with a hospital's facilities to act appropriately in the event of an accident. As peripheral oxygen saturation (SpO₂) and EtCO₂ monitoring reduce the incidence rates of mortality and brain death associated with respiratory problems,¹⁰⁾ a standard for anesthetic care including sedation is necessary to ensure adequate manpower and equipment essential for anesthesia.

It is important to collect detailed data on anesthesia-related injuries. The closed-claims database established by the ASA in 1985 has contributed to improved patient safety.^{9,24)} A system has also been implemented in Korea since 2015 for voluntary reporting of medical accidents; however, it comprises mainly reports of minor accidents and reports of fatal accidents are very rare. The rates of serious adverse events, including death and permanent brain damage, in closed-claims analyses conducted in the US were 56% in 1975 and 27% in 2000.²⁴⁾ The death rates in the older and younger groups in the present study were 82.1% and 67.8%, respectively, higher than those reported in the US. This difference may be because of a greater tendency for cases involving minor problems to proceed to medical disputes in the US than in Korea. However, the percentage of cases resolved through settlement before proceeding to a medical dispute is high in Korea, and medical disputes regarding minor problems can be resolved by government organizations such as the Korea Consumer Agency or the Korea Medical Dispute Mediation and Arbitration Agency, which may also cause the percentage of cases of deaths to differ from that in the US. An increase in medical litigation associated with cases of death, permanent injury, temporary nerve injury, or backache that are not due to malpractice is expected; thus, suitable preparations are necessary to deal with such cases. Analysis of closed-claims studies and cases referred to the KSA could provide a basis for resolving common accidents. However, because of settlements, it is difficult to determine the true incidence of some accident types, even in fatal cases. In addition, if the numbers of accidents associated with a type of drug or anesthesia are increasing, early identification and prevention may be limited. Therefore, a system that allows voluntary reporting of accidents to the KSA is essential. However, even if the KSA were to create such a system, individuals making voluntary reports cannot be legally protected, and the system could be subject to the issue of warrants by the courts. A system that legally protects those reporting to the KSA and thus encourages voluntary reporting, as in other fields of geriatric medicine, is required to prevent medical accidents and improve patient safety.²⁵

Although the awareness of patients' rights is increasing in Korea, an understanding of the difference between medical malpractice and medical maloccurrence (i.e., adverse outcomes that are unrelated to the quality of care provided) remains poor. A Korean court recently ruled that an automobile accident that caused only minor scalp abrasions was responsible for dementia. Legal disputes related to older patients may be more likely in cases of postoperative functional deterioration or dementia and may be affected by whether appropriate patient evaluation is judged to have been performed. Predicting the complications of anesthesia and surgery in older surgical patients requires expanding the implementation of preoperative comprehensive geriatric assessments; furthermore, informed consent and appropriate explanation of anesthesia are also important to improve patient safety and prevent legal disputes.

This study has some limitations. First, the data were extracted from datasheets stored at the KSA. As mentioned above, we could not accurately determine the incidence of anesthesia-related injuries because of the use of claims data. In addition, as this was a retrospective study, the results might have differed if other assessment criteria had been used, including the preventability and appropriateness of anesthesia as assessed by different anesthesiologists.

In conclusion, we identified differences in anesthesia-related disputes between older and younger patients. Preventable events were more likely in younger patients than in older patients. When sedation was not considered, no differences were seen between the older and younger groups. However, the analysis was based on the KSA database and it was not possible to determine causal relationships in the anesthesia-related injury data. Anesthesia-related disputes should be registered via a voluntary reporting system, which must be established by the KSA itself to help prevent accidents.

CONFLICT OF INTEREST DISCLOSURES

The researchers claim no conflicts of interest.

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