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ORIGINAL ARTICLE

Analysis of expert consultation referrals to the Korean Society of Anesthesiologists (KSA): a comparison of procedural sedation and general anesthesia

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Abstract
Purpose Procedural sedation during diagnostic or therapeutic procedures is currently widely used by clinicians across a broad range of specialties. However, procedural sedation is a poorly controlled practice in many countries, often performed in potentially unsafe environments.
Methods In 2009, the Legislation Committee of the Korean Society of Anesthesiologists, based on expert consultation referrals provided by police departments, civil courts, and criminal courts, initiated the construction of database to compile all anesthesia-related adverse events. Using this database (July 2009 to April 2012), we have compared causative mechanisms and injury patterns in procedural sedation (Sedation) cases ($N = 25$) with those in general anesthesia (GA) cases ($N = 29$).
Results The severity of injury in Sedation cases was similar to that in GA cases, with death occurring in 72.0 % of cases. Hypoxia secondary to airway obstruction or respiratory depression was the most common specific mechanism of Sedation-related injuries (64.0 %). In-depth analysis of pre-procedural evaluation and intraoperative monitoring revealed a common lack of vigilance in the Sedation cases, and most injuries were judged as preventable with better monitoring. Non-anesthesiologist administration of propofol (NAAP) was performed in the great majority of Sedation cases (88.0 %).
Conclusion Our analysis of procedural sedation based on anesthesia-related adverse events compiled in the national database revealed a high severity of patient injury similar to that due to general anesthesia. Most procedural sedations were shown to be poorly controlled without adequate pre-procedural patient evaluation or intraoperative monitoring. Thus, it is essential to establish proper practical guidelines for procedural sedation and ensure strict adherence to these guidelines, especially during the NAAP.

Keywords Deep sedation · Injuries · Malpractice · Propofol

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Introduction

The police, public prosecutors, and judges tend to accept the opinion of an independent expert medical board in most medico-legal cases involving potential medical negligence. As members of the medical community, patient advocates, and private citizens, anesthesiologists have ethical and professional obligations to assist the authorities in the administration of justice [1]. The Korean Society of Anesthesiologists (KSA) has therefore continued to reply to these expert consultation referrals in a conscientious manner.

Initially, a single legislation director of the KSA was responsible for all consultations. However, in July 2009, the Legislation Committee of the KSA was established to ensure the consistent validity and impartiality of the consultations and to share the heavy workload by establishing a five-member peer review system. In addition, the Committee was charged with constructing a database from consultation referrals using a standard data collection form for further scientific research.

Since the establishment of this database, it has come to the Committee's attention that the number of referred cases associated with procedural sedation is continually increasing [1]. This has led to an investigation of this issue using the KSA Legislation Committee database. The database was used in the present study is more expanded than that used in the previous KSA analytical report [1] (database of July 2009–April 2012 vs. database of December 2008–January 2010, respectively), however, some data of the earlier study were also included.

In the study reported here, we used the KSA Legislation Committee database to explore the causative mechanisms, injury patterns, and role of substandard care in a subset of procedural sedation case files. We also compared the differences between procedural sedation and general anesthesia case files.

Materials and methods

The establishment of the KSA Legislation Committee in July 2009 coincided with the construction of a database using a standard data collection form. Inclusion criteria for the current study were all cases related to procedural sedation and general anesthesia in the database between July 2009 and April 2012. During this period, 94 cases were referred to our committee for expert consultation. Of these, cases with inadequate detail, non-anesthetic cases, those arising in the pain clinic, and those in which regional anesthesia was performed were excluded. In total, 54 cases were finally included in the study; 25 were classified as associated with procedural sedation (Sedation cases) and 29 were associated with general anesthesia (GA cases) (Fig. 1).

Brief description of the database building process

A referred case file was initially reviewed by a committee member and typically consisted of relevant medical and office records and narrative statements from involved healthcare personnel. Medical records are unfortunately sometimes poor, but piecing together data from statements of the personnel involved often provides a satisfactory picture of the critical events leading up to the complications. When available, an autopsy report was reviewed to confirm medical diagnoses and to help identify specific causation.

After online peer reviewing by all committee members, the reviewer completed a standardized form on which he/she records information about patient characteristics, estimated preoperative American Society of Anesthesiologists (ASA) physical status, type of surgical procedure, anesthesia characteristics (type of anesthesia, anesthesia provider, drugs used, intraoperative monitoring), timing and sequence of damaging events, complications, clinical manifestations of injury, and a narrative summary of each case. The standard data collection form devised by the Committee is configured as a check boxes and a brief description form suitable for use as a paper document (until February 2012) or a web page (available since March 2012).

Description of outcome variables used

Adverse outcomes were classified as 'damaging events' and 'complications.' 'Damaging event' referred to the primary mechanism causing the injury [2]; 'complication' referred to the injury itself.

Damaging events were grouped into 14 categories based on the physiological system or anesthesia technique implicated in the injury: respiratory events, cardiovascular events, central nervous events, peripheral nervous events, allergic or adverse drug reactions, wrong drugs or doses, transfusion reactions, equipment problems, hepatic or renal events, endocrine events, thermal events, musculoskeletal and skin events, infectious events, and others. For further analyses, these 14 categories were subcategorized into more specific areas, many of which are self-explanatory.

Complications were grouped into three categories: temporary/nondisabling, permanent/disabling, and death. In cases of brain damage followed by death within 72 h, the complication was considered to be death.

Intraoperative monitoring was classified into four grades [grade I, no monitoring; grade II, pulse oximetry only; grade III, grade II plus noninvasive blood pressure measurement and/or electrocardiography (ECG); grade IV, grade III plus capnography]. In the Sedation cases, the broad range of terminology used to describe surgical procedures was simplified to four categories: gastrointestinal

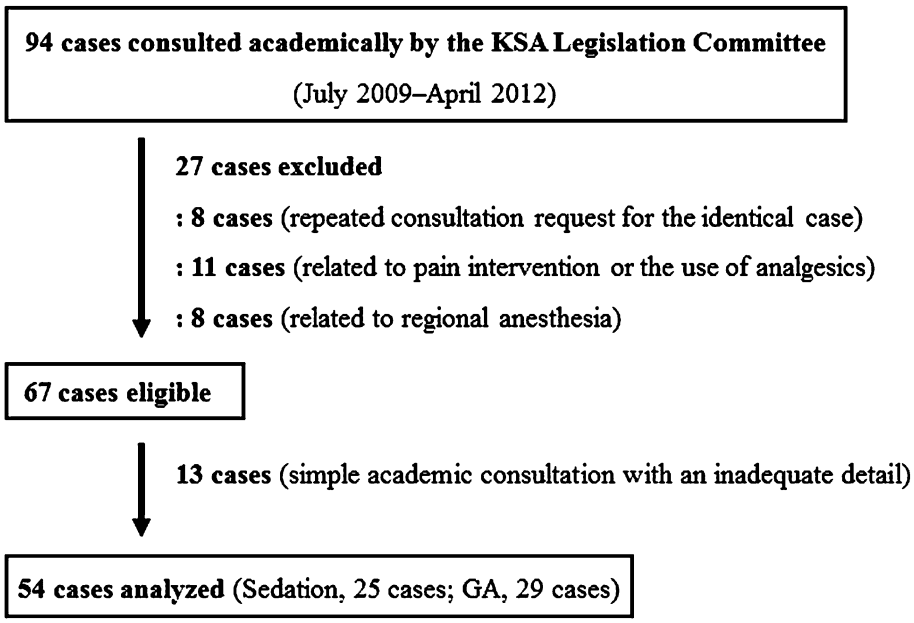

Fig. 1 Flow diagram for case selection. *Sedation* Procedural sedation, *GA* general anesthesia, *KSA* Korean Society of Anesthesiologists

endoscopy, cosmetic surgical procedures, obstetrics and gynecology (OB and GY) procedures, and others.

In each case, patient injuries were judged for theoretical preventability by all members of the committee. The appropriateness of anesthesia care was then graded on a 1–9 point scale with 1–3 indicating 'avoidable,' 4–6 indicating 'possibly avoidable,' and 7–9 indicating 'probably unavoidable,' based on reasonable and prudent practice at the time of event.

Statistical analyses

Categorical variables are described as numbers and percentages and compared using Pearson χ^2-tests with a continuity correction or with Fisher's exact tests, where applicable. 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. The SPSS software (ver. 18.0; SPSS Inc, Chicago, IL) was used for all analyses. Statistical significance was set at $p < 0.05$.

Results

Of the 54 cases included in the final analysis, 25 (46.3 %) were associated with procedural sedation and 29 (53.7 %) were associated with general anesthesia (Fig. 1).

While patient ages were widely distributed (range 1–72 years in GA cases vs. 21–70 years in Sedation cases), the groups did not differ with respect to mean age. In comparison to GA cases, Sedation cases involved a higher proportion of female patients and a higher proportion of ASA physical status I or II (Table 1). These findings are presumably related to a higher proportion of cosmetic surgical procedures in Sedation cases. Sedation was provided by operators (i.e., non-anesthesiologists) in most Sedation cases (22/25, 88.0 %).

Our evaluation of intraoperative monitoring and pre-procedural testing revealed a common lack of vigilance in Sedation cases, as evidenced by pre-procedural testing not having been performed at all in 19 of the 25 patients (76.0 %). Five Sedation patients received virtually no monitoring, while another 12 received only pulse oximetry. The remaining eight patients received minimally pulse oximetry plus blood pressure measurement, and/or electrocardiography monitoring. An in-depth analysis revealed that in six cases, pulse oximetry was ineffective because the practitioner did not use it properly (inappropriate alarm setting or audible pulse tone off). In contrast, at least pulse oximetry, blood pressure, and ECG were simultaneously used for monitoring in all GA cases (Table 1).

The severity of complications developing in the Sedation cases was similar to that in the GA cases, with a similar proportion of temporary/nondisabling, permanent/disabling, and death (8.0, 20.0, and 72.0 % in Sedation cases vs. 0.0, 13.8, and 86.2 % in GA cases, respectively). The appropriateness of anesthesia care, which was graded using a 9-point numerical rating scale, did not differ between groups (Table 1).

A respiratory event was the most common damaging event in both Sedation and GA cases (72.0 vs. 44.8 %, respectively). The main cause of respiratory events in the Sedation cases (16/25, 64.0 %) appeared to be hypoxia

Table 1 General data of procedural sedation (Sedation) and general anesthesia cases

Factors	Sedation ($N = 25$)	GA ($N = 29$)	p value
Age (years)	43.7 ± 13.7	39.2 ± 20.3	0.355
Gender: female/male	19/6	13/16	0.041*
ASA physical status: I or II/III or VI	23/2	17/12	0.006*
Sedation or anesthesia provider: anesthesiologist/non-anesthesiologist	3/22	29/0	<0.001*
Pre-procedural testing: absent/present	19/6	1/28	<0.001*
Grade of intraoperative monitoring: grade I/II/III/IV[a]	5/12/6/2	0/0/15/14	<0.001*
Timing of damaging events: induction/maintenance/emergence/at ward	6/12/6/1	10/4/9/6	0.031*
Appropriateness of anesthesia care[b]	3.0 (2.0–5.0)	5.0 (2.0–6.0)	0.276

Values are expressed as the mean ± standard deviation (SD), as the number of cases, or as median with the iinterquartile range (IQR) given in parenthesis

ASA American Association of Anesthesiologists, *GA* general anesthesia

[a] Intraoperative monitoring (presented as the number of cases): 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

[b] Appropriateness of anesthesia care (presented as the median with the IQR) was graded on a 1–9 point scale

* $p < 0.05$

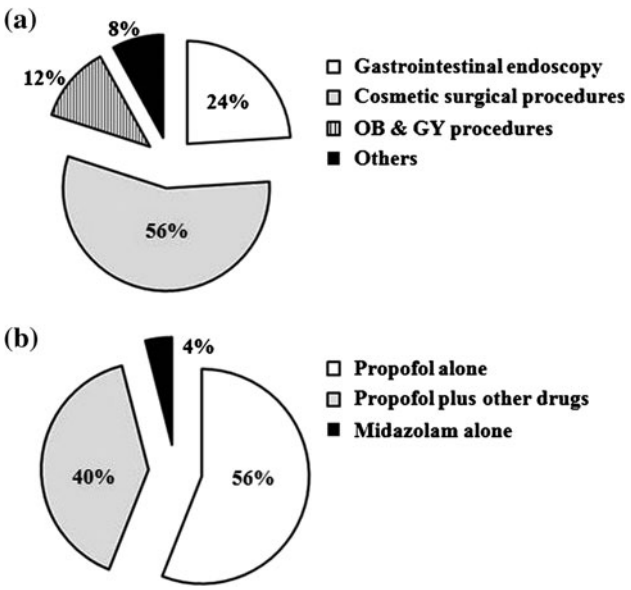

Fig. 2 Analysis of the clinical specialties involved (**a**) and sedative drugs used (**b**) in procedural Sedation cases ($N = 25$). *OB* obstetrics, *GY* gynecology; 'Others' include one case of bone marrow biopsy

secondary to airway obstruction or respiratory depression. Other causes of respiratory events in Sedation cases included an inability to intubate and ventilate the patient due to a massive aspiration of gastric contents, and a fatal pulmonary edema. The second most common damaging event in both Sedation and GA cases (12.0 vs. 34.5 %, respectively) was a cardiovascular event due to a variety of diverse specific causes (acute myocardial infarction, pulmonary embolism, critical arrhythmia, hypovolemia due to massive bleeding, and unexplained cardiac arrest). Other damaging events in Sedation cases included three cases of hepatic or renal event (acute hepatic failure), endocrine event (hypoglycemia), and infectious event (infected propofol solution).

The distribution of cases among clinical specialties in the Sedation group showed that cosmetic surgical procedures were the most common type of surgery (56.0 %), followed by gastrointestinal endoscopy (24.0 %; Fig. 2a). Apart from one case (midazolam alone), propofol was used in all Sedation cases, either alone ($N = 14$) or in combination with a benzodiazepine, ketamine, or opioids ($N = 10$) (Fig. 2b). In terms of sedation provider, the non-anesthesiologist administration of propofol (NAAP) was performed in 21 of 25 Sedation cases (84.0 %).

Discussion

Procedural sedation is the use of anxiolytic, sedative, analgesic, or dissociative drugs to attenuate pain, anxiety, and motion in order to facilitate the performance of a necessary diagnostic or therapeutic procedure and to provide an appropriate degree of amnesia or decreased awareness [3, 4]. Procedural sedation is clearly distinct from monitored anesthesia care (MAC) in that the latter is essentially provided by anesthesiologists [5]. By definition, procedural sedation not only includes sedation provided by anesthesiologists (i.e., MAC) but also sedation provided by non-anesthesiologists [4].

Worldwide, procedural sedation is administered by a diverse group of practitioners to patients of all ages in a variety of clinical specialties. Our results show that in 88 % of procedural sedation cases, sedation and diagnostic/therapeutic procedures were simultaneously performed by a

single practitioner (i.e., non-anesthesiologist). However, sedation includes a continuum of states of consciousness, progressing from mild through moderate to deep sedation and—potentially—to general anesthesia, and it is not always possible to predict how an individual patient will respond [2, 3, 6, 7]. Although target levels of sedation have been defined, the actual level of sedation in patients may easily fluctuate. Thus, several practice guidelines [3, 6, 8–10] commonly recommend that patients should be monitored continuously by medical personnel who are not directly involved in the procedure and that the sedation provider should be qualified to rescue patients whose level of sedation becomes deeper than initially intended.

One closed-claims analysis [2] demonstrated that the most common source of injury during procedural sedation is respiratory depression as a result of over-sedation. Similarly, in our analysis, 16 of 25 Sedation cases (64.0 %) were attributed to airway obstruction ('can't breathe' situation) or respiratory depression ('won't breathe' situation) due to relative over-sedation, resulting in death, with the exception of two cases.

As most procedural sedation cases are for simple or superficial operations that are performed in apparently healthy patients, a pre-procedural patient evaluation is often omitted, and informed consent is poorly understood by patients. Legally, the responsibility for procedural sedation begins with the pre-procedural evaluation. Published practice guidelines [3, 6, 8–10] indicate that although routine pre-procedural testing is not necessary, sedation-oriented medical history-taking and a focused physical examination should be performed in all patients. However, in our analysis, no pre-procedural testing was performed in 76.0 % of the Sedation cases. Even though pre-procedural testing may be omitted, documentation on the results of the patient's history-taking and physical examination should exist. However, in only two cases included in our study was such documentation found, and then only in a very brief format. In future cases, this can work against practitioners in court. In this regard, a specific standardized form of pre-procedural evaluation record (configured as check boxes and brief description formats for easy documentation) should be developed through a consensus-building process involving the relevant academic societies.

Regarding the degree of monitoring during procedural sedation, there are some disparities among current practice guidelines of different specialties. However, continuous monitoring of pulse oximetry is emphasized as standard-of-care monitoring during procedural sedation [3, 8–10]. With respect to the utility of continuous ECG monitoring and blood pressure measurements, the relevant professional societies have said they are 'optional.' They can be used in selected patients with a history of cardiac and/or pulmonary disease [3, 8–10].

However, professional societies are deeply divided on the utility of capnography as a standard monitoring technique during procedural sedation. All societies of endoscopists [9], plastic surgeons [10], and emergency medicine doctors [8] propose that the use of capnography is not standard in conventional procedural sedation. However, anesthesiologists have commonly emphasized that the minimum in procedural sedation monitoring is independent of the depth of sedation and should include capnography [3, 11]. The rationale for this is that the primary cause of morbidity/mortality associated with procedural sedation is drug-induced airway obstruction or respiratory depression [1, 2, 11], and significant hypoventilation may be undetected by pulse oximetry, particularly when supplemental oxygen is administered [11, 12]. In this regard, we believe that monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilation.

Our results show that NAAP was performed in 21 of 25 Sedation cases (84.0 %). Although strict patient selection (usually limited to ASA 1 or 2 patients) is strongly recommended in NAAP [3, 6, 8–10], our results indicate that all of the NAAP did involve ASA 1 or 2 patients, suggesting that the safety of NAAP should be reconsidered.

There are ample data confirming the superiority of propofol to traditional sedation regimens (benzodiazepines and/or opioids) in terms of reducing induction and recovery times and improved patient satisfaction [9, 10, 13]. Thus, as suggested by Coté [14], the dispute is not whether to use propofol but rather who can administer it. Although almost half a million cases have been reported with a very low overall risk of cardiopulmonary complications by NAAP [15], the ASA and the European Society of Anesthesiologists give strong support to the maintenance of the Federal Drug Administration regulation that propofol is restricted solely to personnel trained in general anesthesia [6, 16]. However, professional academies supporting the safety of NAAP have proposed that even non-anesthesiologists are capable of administering propofol after the completion of specialized training [9, 10, 13, 14].

This study has a number of limitations in terms of interpretation. First, our database does not include data on the total number of adverse outcomes or the total number of general anesthesia or procedural sedation cases performed, making it impossible to provide any numerical estimates of the actual risks. Because only a minority of adverse events ever result in medico-legal problems, our case files represent only a very small proportion of incidents involving patient harm [17]. Second, our data were collected retrospectively, and the database contains only information that reviewers could obtain from medical and office records. In particular, they tend to lack impartiality when it comes to narrative statements from involved healthcare personnel [18]. Third, the recent availability of

the Court's Precedents' database allows similar analyses to those conducted. However, the value of such a database as a tool for improving patient's safety is limited compared with our database because the former includes only cases that have been the subject of legal claims. Cases in the Court's Precedents' database are prepared by lawyers for lawyers. Data collected by clinicians for clinicians, such as our database, are likely to be of greater value, as has been shown by long-running audits, such as the ASA Closed Claims Project [19]. Lastly, it may be more useful to compare the injury profiles between sedation cases provided by anesthesiologists (MAC) and those by non-anesthesiologists. Even though the number of MAC cases in our database is too small to conduct such an analysis, future study is necessary to clarify this issue.

In summary, our database analysis of procedural sedation shows a high severity of patient injury similar to that of general anesthesia. Most procedural sedations were shown to be poorly controlled and often performed in potentially unsafe environments without adequate pre-procedural patient evaluations or intraoperative monitoring. The main mechanism of injury during procedural sedation was hypoxia secondary to airway obstruction or respiratory depression by NAAP.

In any type of medical practice, patient safety is the number one priority. To ensure this, appropriate practical guidelines for procedural sedation should be established, and strict adherence to them should be ensured, especially for NAAP. Additionally, the insights gained from analyzing our database will continue to provide important contributions to patient safety in anesthesia practice.

Conflict of interest None.

References

1. Lee KH, An TH, Choi JH, Lim DG, Lee YJ, Kim DK. Analysis of expert consultation referrals for anesthesia-related issues (December 2008–July 2010): KSA legislation committee report. Korean J Anesthesiol. 2011;60:260–5.
2. Bhananker SM, Posner KL, Cheney FW, Caplan RA, Lee LA, Domino KB. Injury and liability associated with monitored anesthesia care: a closed claims analysis. Anesthesiology. 2006; 104:228–34.
3. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. Anesthesiology. 2002;96:1004–17.
4. Green SM, Krauss B. Procedural sedation terminology: moving beyond "conscious sedation". Ann Emerg Med. 2002;39:433–5.
5. American Society of Anesthesiology. Distinguishing monitored anesthesia care ("MAC") from moderate sedation/analgesia (conscious sedation). Available at: http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx. Accessed 4 Sept 2012.
6. Perel A. Non-anaesthesiologists should not be allowed to administer propofol for procedural sedation: a Consensus Statement of 21 European National Societies of Anaesthesia. Eur J Anaesthesiol. 2011;28:580–4.
7. Hug CC Jr. MAC should stand for maximum anesthesia caution, not minimal anesthesiology care. Anesthesiology. 2006;104: 221–3.
8. Godwin SA, Caro DA, Wolf SJ, Jagoda AS, Charles R, Marett BE, Moore J, American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. Ann Emerg Med. 2005;45:177–96.
9. Standards of Practice Committee of the American Society of Gastrointestinal endoscopy, Lichtenstein DR, Jagannath S, Baron TH, Anderson MA, Banerjee S, Dominitz JA, Fanelli RD, Gan SI, Harrison ME, Ikenberry SO, Shen B, Stewart L, Khan K, Vargo JJ. Sedation and anesthesia in GI endoscopy. Gastrointest Endosc. 2008;68:815–26.
10. Iverson RE. Sedation and analgesia in ambulatory settings. American Society of Plastic and Reconstructive Surgeons. Task Force on Sedation and Analgesia in Ambulatory Settings. Plast Reconstr Surg. 1999;104:1559–64.
11. Eichhorn V, Henzler D, Murphy MF. Standardizing care and monitoring for anesthesia or procedural sedation delivered outside the operating room. Curr Opin Anaesthesiol. 2010;23:494–9.
12. Downs JB. Has oxygen administration delayed appropriate respiratory care? Fallacies regarding oxygen therapy. Respir Care. 2003;48:611–20.
13. Dinis-Ribeiro M, Vargo JJ. Sedation by non-anesthesiologists: are opioids and benzodiazepines outdated? Digestion. 2010;82: 100–1.
14. Coté GA. The debate for nonanesthesiologist-administered propofol sedation in endoscopy rages on: who will be the "King of Prop?". Gastrointest Endosc. 2011;73:773–6.
15. Rex DK, Deenadayalu VP, Eid E, Imperiale TF, Walker JA, Sandhu K, Clarke AC, Hillman LC, Horiuchi A, Cohen LB, Heuss LT, Peter S, Beglinger C, Sinnott JA, Welton T, Rofail M, Subei I, Sleven R, Jordan P, Goff J, Gerstenberger PD, Munnings H, Tagle M, Sipe BW, Wehrmann T, Di Palma JA, Occhipinti KE, Barbi E, Riphaus A, Amann ST, Tohda G, McClellan T, Thueson C, Morse J, Meah N. Endoscopist-directed administration of propofol: a worldwide safety experience. Gastroenterology. 2009;137:1229–37.
16. Werner C, Smith A, Van Aken H. Guidelines on non-anaesthesiologist administration of propofol for gastrointestinal endoscopy: a double-edged sword. Eur J Anaesthesiol. 2011;28:553–5.
17. Localio AR, Lawthers AG, Brennan TA, Laird NM, Hebert LE, Peterson LM, Newhouse JP, Weiler PC, Hiatt HH. Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III. N Engl J Med. 1991;325:245–51.
18. Jordan LM, Kremer M, Crawforth K, Shott S. Data-driven practice improvement: the AANA Foundation closed malpractice claims study. AANA J. 2001;69:301–11.
19. Bogod D. Negligence litigation and medicine: force for good or root of all evil. Anaesthesia. 2011;66:247–9.