

Composition and Risk Assessment of Perioperative Patient Safety Incidents Reported by Anesthesiologists from 2009 to 2019, a single-center retrospective cohort study

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Abstract

Background: Patient safety incident reporting has been an important means of improving patient safety and enhancing organizational quality control. Reports of anesthesia-related incidents are of great value for analysis to improve perioperative patient safety. However, the utilization of incident data is far from sufficient, especially in developing countries such as China.

Methods: All patient safety incidents reported by anesthesiologists in a Chinese academic hospital between September 2009 and August 2019 were collected from the incident reporting system. We reviewed the freeform text reports, supplemented them with information from the patient medical record system. Composition analysis and risk assessment were performed.

Results: In total, 847 patient safety incidents were voluntarily reported by anesthesiologists during the study period among 452,974 anesthetic procedures, with a reported incidence of 0.17%, much less than the incidence reported by some developed countries. Patients with worse ASA physical status were more vulnerable to suffering from PSIs. The most common type of incident was related to the airway (N=208, 27%), followed by cardio-cerebrovascular (N=99, 13%) and pharmacological incidents (N=79, 10%). Those preventable incidents with extreme or high risk were found out through risk assessment, to provide reference for the department to implement more standard operation procedures.

Conclusions: This study describes characteristics of 847 patient safety incidents voluntarily reported by anesthesiologists within eleven years in a Chinese academic hospital. Airway incidents constitute the majority of incidents reported by anesthesiologists. Under-reporting is severe in China, and the importance of summarizing and utilizing anesthesia incident data should be scrutinized.

Background

According to the World Health Organization (WHO) international classification for patient safety, a patient safety incident (PSI) is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient [1]. PSI reporting has been an important means of improving patient safety and enhancing organizational quality control. Many developed countries, such as the United States of America, Australia, the United Kingdom and Germany, already have national PSI reporting systems for prospective collection of PSI data even since 1993 [2–6]. These systems similarly encourage the blame-free submission of incident reports, with the aim of finding such defects before causing harm [3].

By understanding the theory more thoroughly and thanks to the development of new technologies, anesthesia has become safer in recent decades. However, the quality of anesthesiologists' work could be challenged by the increasing number of old and sick patients, more complicated surgical procedures, new drugs and new equipment, increasing pressure and professional burnout. The Declaration of Helsinki as amended in June 2010 emphasized that all institutions providing anesthesia care to patients must contribute to the recognized national or other major audits of safe practice and to critical incident reporting systems [7]. In a 2019 European survey, 78.7% of responders stated that their hospital used a

critical incident reporting system [8]. In the United Kingdom, a specialty-specific incident reporting system for anesthesia was introduced in 2010 [9]. However, few studies have characterized incidents from anesthesia practice, and none of these have been from developing countries.

As far as we know, nation-wide incident reporting systems are not well established and managed in most developing countries, including China. It has become a huge waste of clinical information because timely identification of errors makes pre-emptive efforts for clinical change and improvement possible. As the top hospital in China, Peking Union Medical College (PUMC) Hospital established a PSI reporting system in 2009. Hereby, we analysed all patient safety incidents reported by anesthesiologists in PUMC Hospital in an eleven-year period to share information with other anesthesiologists to better improve patient safety in perioperative care.

Methods

Data Collection

An incident reporting system was established in 2009 in PUMC Hospital. All healthcare workers are authorized to log in the system and report patient safety incidents either anonymously or not. The incidents were described in freeform text to provide information on patient circumstances, details of the incident, perceived contributing factors, hidden danger, and suggestions for prevention. The database was examined for all incidents reported by anesthesiologists from September 2009 to August 2019 with the approval of the Peking Union Medical College Hospital Institutional Review Board (S-K1107, 25 March 2020). Data were also collected from the patients' records, including anesthesia records, to supplement the information in the incident reports.

Data Cleaning

The incidents were reviewed by professional reviewers for reclassification. We have eight reviewers from the department of anesthesiology to clean the data into Excel table form. All members of the research group signed confidentiality agreements before receiving the data. To ensure validity and reliability throughout the study, two independent reviewers reviewed the same part of the data separately, and all the members received uniform training about the data extraction. The two reviewers met to discuss discrepancies until they reach an agreement. When discrepancies could not be resolved by discussion between the two reviewers, the problem was discussed at a weekly meeting of the whole research group under the direction of the senior investigators.

The process of data cleaning included two parts. The first part was incident classification and detail collection. We collected patient sex, date, time and place of incident occurrence, type of surgery, and phase of anesthesia when the incident occurred for further group analysis. Incidents were classified into seven types: airway incidents, cardio-cerebrovascular incidents, pharmacological incidents, equipment incidents, spinal or regional anesthesia incidents, incidents related to surgery and other incidents. For each type of incident, more detailed information was collected.

The second part of data cleaning was risk assessment. Risk assessment was performed based on the estimated risk of recurrence and estimated consequences for the patient. Then, the incident is automatically classified into four risk categories: extremely high, high, medium and low risk (Table 1) [11]. The reviewers also classified subjectively whether the incidents were preventable, unpreventable or undecided.

Table 1
Risk assessment matrix.

Consequences/ risk of recurrence	Almost inevitable	Probable	Possible	Small	Very small
Catastrophe	Extremely high	Extremely high	Extremely high	Extremely high	Extremely high
Very serious	High	High	High	High	High
Serious	High	High	High	Medium	Medium
Marginally serious	High	High	Medium	Medium	Low
None	Medium	Medium	Medium	Low	Low

Statistical Analysis

Data were stored in a relational structure using Microsoft Office Excel 2016 (Microsoft Corp. 2016). SPSS (IBM SPSS statistics Version 26) was used for statistical analysis of the dataset. We described the demographic and basic clinical characteristics of the patients involved in the safety incidents. The “percentage of patients with incidents” for different ASA categories was calculated by the number of patients with reported incidents divided by the total number of patients with the same ASA grade, and the risk ratio with the 95% confidence interval (CI) was estimated using the ASA I as the reference group. A two-sided P value less than 0.05 was regarded as statistically significant.

Results

Of the 847 patient safety incidents voluntarily reported by anesthesiologists from September 2009 to August 2019, 74 cases were excluded because they were reported repetitively or not related with anesthesia. In total, 773 cases were enrolled among 452,974 anesthesia care episodes, with an overall PSI reporting incidence of 0.17%. Case number of different types of incidents are shown in Fig. 1.

The average age of the 773 patients involved in the incidents was 51.79 ± 31.91 (mean \pm SD), and the median age was 54. Regarding ASA physical status, patients with worse physical status were more vulnerable to suffering from PSIs (Table 2). Other details related to patients and the reported incidents are shown in table 3.

Table 2
ASA physical status of patients with reported incidents.

ASA	No. of patients with incidents	No. of patients without incidents	% of patient with incidents	Risk ratio (95% CI)
I	78	105467	0.074	1.00
II	253	118620	0.213	2.88 (2.24 to 3.72)*
III	89	14332	0.617	8.40 (6.19 to 11.39)*
IV	37	981	3.635	51.00 (34.31 to 75.80)*
V	5	78	6.024	86.68 (34.16 to 219.91)*

*p < 0.05. CI: confidence interval. ASA: American Society of Anesthesiologists.

Since the ASA data of patients without incidents were available only after 2013 due to technological issues (the electronic anesthesia record system in PUMC Hospital was established in 2013, so the ASA status of patients without incidents reported could only be collected after 2013), only data from 2013 to 2019 were used for analysis related to ASA status related analysis.

Table 2
Demographic variables and other details on the reported incidents.

Item (N = 773)	Detail	Number of incidents (%)
Patient sex	Male	315 (40.8)
	Female	357 (46.2)
	NA	101 (13.1)
Date of occurrence	Weekday	692 (89.5)
	Weekend	22 (2.8)
	NA	59 (7.6)
Time of occurrence	Working hours (8:00am-4:00 pm)	445 (57.6)
	Nonworking hours (4:01 pm-7:59am)	312 (40.3)
	NA	16 (2.1)
Place of occurrence	In the OR (including PACU)	649 (84.0)
	Out of the OR	93 (12.0)
	NA	31 (4.0)
Type of surgery	Elective surgery	620 (80.2)
	Emergency surgery	110 (14.2)
	Labor analgesia	4 (0.5)
	NA	39 (5.0)
Phase of anesthesia when incident occurred	Pre-induction	62 (8.0)
	Induction	77 (10.0)
	Maintenance	247 (32.0)
	Emergence	73 (9.4)
	Recovery in PACU	31 (4.0)
	Post-operative period	77 (10.0)
	During spinal or regional anesthesia procedure	45 (5.8)
	NA	161 (20.8)
	OR: operating room. PACU: post-anesthesia care unit.	

The total number of incidents with available information in each part is not equal to 773 because some of the data was incomplete or missing.

Airway Incidents

Twenty-seven percent (208 of 773) of PSIs were airway-related incidents. Sixty-five (31.3%) occurred during intubation, 41 (19.7%) occurred during anesthesia maintenance, 73 (35.1%) occurred during extubation, and 28 (13.5%) incidents were reported after the patient returned to the ward. There was also one patient (0.5%) who had airway obstruction in the OR before anesthesia induction. The most common airway incident categories were bronchospasm or laryngospasm (N = 32), post-intubation hoarseness (N = 28), dental injury (N = 20), intubation failure (N = 17), intubation delay caused by difficult airway (N = 15), airway obstruction (N = 14), and aspiration (N = 10). Ninety-six (46.15%) of the patients suffered from airway-related hypoxemia, comprising 34 mild cases (with minimal SpO₂ ≥ 85% for less than 5 min) and 62 severe cases (with minimal SpO₂ < 85% or hypoxemia for more than 5 min). Nine patients had bradycardia, and 3 patients even had cardiac arrest caused by hypoxemia. We also noticed that 61 patients received unplanned secondary intubation for different reasons. Some of those reasons were related to anesthesia procedures, such as airway obstruction or spasm (N = 18), hypoxemia after extubation (N = 13), residual paralysis of muscle relaxation (N = 6), unplanned change of airway maintaining devices (N = 3), endotracheal tube prolapse or dislocation (N = 2), and other reasons related to anesthesia (N = 3). Others were related to the patients or surgery related (N = 16).

Cardio-cerebrovascular Incidents

In total, 72 cardiovascular events and 27 cerebrovascular events were reported as PSIs. However, cardio-cerebrovascular events could also be found in other types of incidents. For example, surgical haemorrhage is always accompanied by hypotension. As a result, we combined cardio-cerebrovascular-related incidents for analysis in this part. The most common types of cardiovascular incidents were hypotension and cardiac arrhythmia, with 205 and 158 incidents for each type, respectively. Intraoperative blood loss was the most common cause of hypotension (N = 112, 54.6%), followed by anaphylactic shock (N = 47, 22.9%). As for cardiac arrhythmia, sinus tachycardia and bradycardia were most frequently reported, consisting of 49 and 32 incidents, respectively. CPR occurred in 67 patients, with a rate of 1.48 per 10000 anesthesia episodes. Twenty-four (35.8%) of the CPR cases were cardiogenic, and 43 (64.2%) cases were caused by other reasons, such as surgical haemorrhage and severe hypoxemia due to airway problems.

Pharmacological And Transfusion Incidents

Fifty-five pharmacological incidents and 24 transfusion-related incidents were collected from the system. The majority of incidents falling in the pharmacological category were anaphylactic reactions, among which 20 and 13 were related to antibiotics and blood products, respectively. Other incidents occurred during drug supply (N = 1), drug storage (N = 1), drug preparation (N = 4), blood product preparation (N =

2), and drug administration (N = 4). Six severe adverse drug reactions and 2 cell-saver related incidents were also reported.

Other Incidents

Incidents occurring more than 5 times among 198 other types of incidents are listed as follows. A total of 143 incidents revealed problems in multidisciplinary corporation and communication. Twelve incidents were related to anesthesia records. Six reported occupational exposure.

Risk Assessment

Risk assessment data are shown in Table 4. We paid special attention to preventable incidents with extreme or high risk. For airway incidents, 7 were accompanied by secondary intubation, 5 were related to aspiration, and 4 incidents occurred due to unexpected difficult airway intubation failure. For cardio-cerebrovascular incidents, 10 and 9 were accompanied by hypotension and arrhythmia, respectively. Five patients received CPR. Three patients suffered from peri-operative cerebral infarction, and 2 patients were diagnosed with myocardial infarction. For pharmacological incidents, 4 of those incidents were related to the blood distribution procedure. Two incidents occurred during drug preparation and caused incorrect drug administration and resulted in patient harm.

Table 4
Risk and preventability assessment for patient safety incidents.

Risk/preventability	Preventable (N)	Unpreventable (N)	Undecided (N)
Airway incidents			
Extremely high	2	0	0
High	23	55	6
Medium	47	68	6
Low	1	0	0
Cardio-cerebrovascular incidents			
Extremely high	5	4	4
High	8	19	15
Medium	14	26	0
Low	2	2	0
Pharmacological incidents			
Extremely high	1	0	0
High	8	51	3
Medium	7	2	3
Low	2	1	1

Discussion

To err is human, and error is unavoidable. Patient safety incident reporting can help physicians learn from error and improve patient safety. PUMC Hospital is one of the first hospitals establishing a patient incident reporting system in China, and its department of anesthesiology has been in the top three departments according to the number of incidents reported for many years. However, the incident reporting incidence of our department during the last 11 years was only 0.17%, much less than those reported from developed countries [10, 12, 13]. In developing countries such as China, there are numerous reasons contributing to under-reporting, including inconvenient reporting systems, inconstant reporting standards, poor safety culture among institutions, fear of punishing action, and inadequate systematic analysis of the reports and feedback [9, 14, 15]. Moreover, Chinese doctors are suffering from increasing burnout and decreasing job satisfaction [16], which reduces the amount of attention paid to things other than daily clinical work. Only a few people work on quality control and patient safety improvement in China, especially in underdeveloped regions. Most physicians have little knowledge on how the reported

incidents will be analysed and how the results are going to generate changes to improve patient safety eventually. Consequently, the phenomenon of under-reporting is very severe in China. Implementation of a better and more convenient PSI reporting system, unification of reporting standards, encouragement for blame-free reporting, periodic summarizing and timely feedback of PSI data to the public may help increase the PSI reporting rate.

Airway incidents were the most common type of incidents reported and were the top concern for anesthesiologists. This is consistent with other anesthesia-related incident research [10], but different from incident composition reported by other departments, such as the ICU [17]. ICU incident analysis has found that airway incidents caused more harm for patients than other types of incidents [18], so anesthesiologists should pay more attention to airway incidents.

Pharmacological incidents are always associated with harm for patients [19]. Runciman and colleagues reported that 36% of anesthesia-related incidents were associated with adverse drug events [20]. Webster and colleague found that one drug administration error was reported for every 133 anesthetics [21]. However, only 79 pharmacological incidents (including transfusion-related incidents) were reported in our PSI system, much less than the PSI reporting rate in other researches. There are mainly two reasons for this result. Firstly, many events were not reported simply because the doctor didn't notice that PSI had occurred, or due to the misconception that such events do not cause severe patient harm so that reporting is not necessary. Secondly, lots of precautions were taken to prevent them from happening. We have been using international color-code standard for anesthetic labels to avoid drug confusion [22]. Double check by at least two anesthesia doctors or nurses must be done before using drugs, and ampoules were not allowed to be thrown away before the patient went out of the operating room. These measures help us to minimize the incidence of pharmacological PSIs in our department.

Risk assessment is useful for helping physicians determine the types of incidents that are harmful for patients but preventable, so intervention could be performed from the department perspective. Take airway incidents for example. We found from our analysis that among those preventable incidents with extreme or high risk, 7 were accompanied by secondary intubation. Therefore, we reported all second intubation cases during the daily morning shift in detail so that every physician could learn from these cases and pay more attention to them in their clinical work. We also noticed that many cases were related to unexpected difficult airway intubation failure. Therefore, we conducted difficult airway management training for physicians to improve their mastering skills.

We can also identify some common types of incidents that are worth analysing from our results. For example, we had 28 post-intubation hoarseness incidents reported, among which 25 were caused by arytenoid dislocation (AD). AD is a rare but severe complication after general anesthesia with endotracheal intubation. This complication frequently appeared in our incident reporting system and had already attracted our attention. We conducted a case-control study and identified that AD was associated with prolonged operation time and that an intubation stylet appeared to protect against AD [23].

Consequently, our department encouraged anesthesiologists to use an intubation stylet, especially for patients who underwent long-term surgery.

On the other hand, standard operation procedures (SOPs) could be implemented to provide physicians with guidance for dealing with clinical situations that may cause PSIs. For instance, most of the pharmacological incidents reported in our research were anaphylaxis reactions, which often have quick onset and can cause serious threats to life if not treated rapidly and correctly. Therefore, our department has implemented a SOP for intra-operative anaphylaxis, which not only reminds anesthesiologists to pay attention to drug allergy prevention but also guides them for treatment and resuscitation when anaphylaxis occurs. We had already implemented lots of SOPs (such as difficult airway management, bronchospasm and laryngospasm, post-intubation hoarseness, anesthesia-related dental injury, aspiration, etc) based on the result of PSI analysis. More SOPs would be introduced in the future, and the effectiveness of SOPs should be further evaluated.

This study also has some limitations. First, the freeform text incident data were subjective and incomplete. This was a common problem that all PSIs had, so misunderstanding and imperfection were unavoidable to a large extent. To make up for the deficiency as much as possible, we supplemented incident information through reading patients' records and tried our best to ensure the validity and reliability during data cleaning as described above. Second, our study was a single-centre study, and the phenomenon of under-reporting was severe. What's more, nonroutine events without patient injury or even with mild patient physiologic disturbances might not be reported, although these events were also important for guiding organizational patient safety improvement interventions [24]. Consequently, the result might not reflect the whole picture. Under-reporting is unavoidable, but our hospital has taken many measures to increase the reporting rate. For example, our hospital has specially assigned administration staff to manage those reported incidents and feedback to the related department and individual. The hospital also provides financial incentives to encourage incident reporting. Our department also had quality control group, and has periodically analysed PSI information and shared summary reports with the whole department to give feedback. Therefore, our reporting rate is relatively high in China. More complete incident reporting systems should be established, and better incident reporting cultures should be cultivated in developing countries. Large, multi-centre trials may be needed, and more attention should be paid to better summarize the incident and to make the data more valuable in the future.

Conclusions

We analysed 847 patient safety incidents voluntarily reported by anesthesiologists within eleven years in a Chinese teaching hospital. The reporting rate was only 0.17%, reflecting that under-reporting is still severe in China. Airway incidents constitute the majority of incidents which is in consistent with other developed countries. The importance of summarizing and utilizing anesthesia incident data should be scrutinized. Measures should be done from department or higher organizational perspective based on PSI analysing results, such as PSI events summary and feedback, and SOP implementation.

List Of Abbreviations

WHO : World Health Organization

PSI: patient safety incident

PUMC: Peking Union Medical College

AD: arytenoid dislocation

SOP: standard operation procedures

Declarations

Ethics approval and consent to participate

This investigation was a retrospective hospital-based study approved by Peking Union Medical College Hospital Institutional Review Board (S-K1107, 25 March 2020). No written informed consent was obtained from participants since that it is a retrospective study without any individual person's data. All the data were collected from the patient safety incident reporting system in our hospital.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

XZ (Xue Zhang) collected data, did data cleaning and was the major contributor in writing the manuscript. SM collected data and work on data analysis. YZ directed the study design and participated in the statistical analysis. WC directed the design and modified the article. XS, QC, HP and XZ (Xiuhua Zhang) helped on data collection and gave methodology supervision. LS and YH were project administration, directed the design of the study and gave supervision to the study.

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Figures

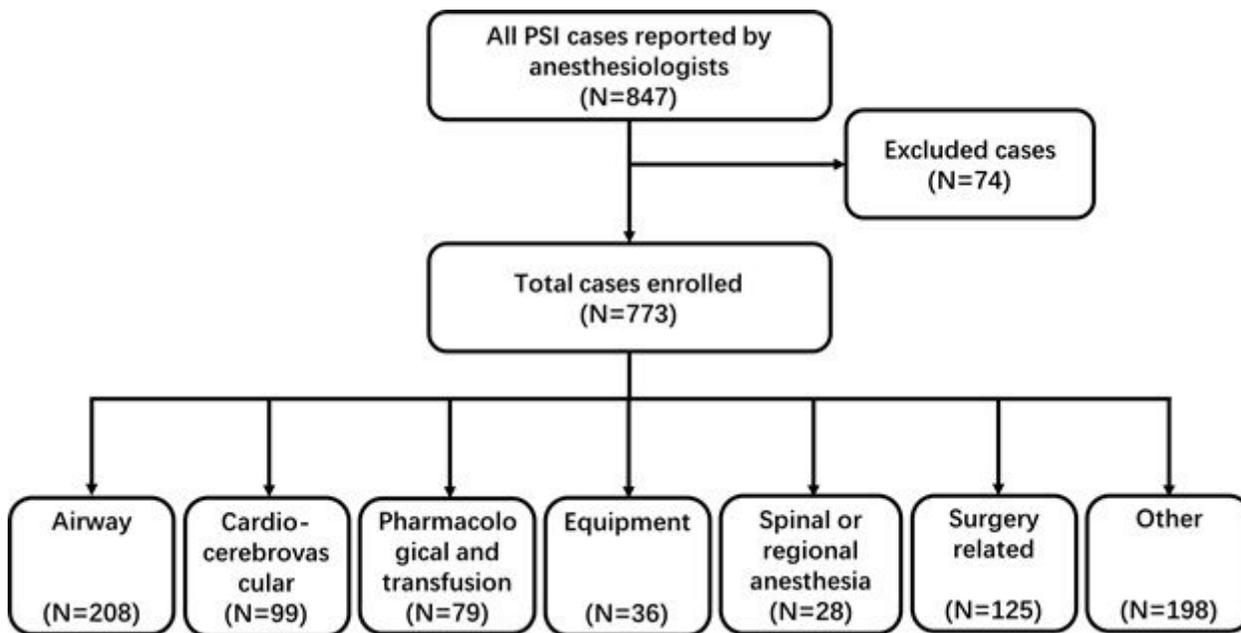


Figure 1

Case enrollment and classification. The figure shows number of cases reported by anesthesiologists during the 11-year study period and the classification of the final case cohort for analysis.