

Original article

Perioperative and Anesthetic Adverse events in Thailand (PAAd Thai) incident reporting study: anesthetic profiles and outcomes

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Background: The Royal College of Anesthesiologists of Thailand initiated registry and reporting of anesthesia service incidents and outcomes in 2005.

Objectives: The Perioperative Anesthetic Adverse Events in Thailand (PAAd Thai) study aimed to investigate patient, surgical, and anesthetic profiles, and suggest strategies for prevention of adverse events.

Methods: A prospective descriptive study was conducted in 22 hospitals across Thailand. Each hospital was invited to report, on an anonymous basis, any perioperative adverse incident during 12 months (between January 1 and December 31, 2015). A standardized incident report form was completed to determine the type of incident, and where, when, how, and why it occurred using closed and open-ended questionnaires. Data regarding main anesthetic techniques were also reported monthly. Descriptive statistics were used.

Results: For 333,219 cases, 2,206 incident reports with 3,028 critical incidents were reported. The incidents commonly occurred in male patients (52.0%), aged <10 y (13.0%) and >70 y (18.2%). The incidence of adverse events included cardiac arrest within 24 h (15.5:10,000), death (13.0:10,000), reintubation (11.1:10,000), esophageal intubation (8.5:10,000), difficult intubation (8.0:10,000), and malignant hyperthermia (1:200,000). General, cardiothoracic, neurological, and otorhinolaryngological surgical specialties posed a high risk of incidents. Operating and recovery rooms were common locations for incidents.

Conclusion: In the past decade, there were dramatic reductions of perioperative cardiac arrests and difficult intubations. Common factors related to critical incidents were inexperience, emergency, inadequate preanesthetic evaluation, inappropriate decisions, lack of vigilance, and inexperienced assistants. Suggested corrective strategies are compliance with guidelines, additional training, and improvement of supervision and quality assurance.

Keywords: Adverse events, anesthesia, incidents, incident report, patient safety

Anesthesiologists are accepted as aiming to be outstanding in patient safety and medical quality improvement. However, both preventable and inevitable adverse events still persist [1, 2]. According to the Thai Anesthesia Incidents Study (THAI Study) database, the incidence of perioperative cardiac arrest within 24 h was 31:10,000 in 2005 with a mortality rate of 90% [3, 4]. The Royal College of Anesthesiologists of Thailand (RCAT) initiated knowledge management tools using research to improve anesthesia processes and outcomes. Several strategies have been engaged to improve patient safety across the country. The subsequent Thai Anesthesia Incidents Monitoring Study (Thai AIMS) was initiated in 2007 using incident reports among 51 hospitals across Thailand using the concept of “from routine to research, and from research to routine practice” [5, 6]. There were several consequent changes to anesthesia practice guidelines and technology, such as using pulse oximetry as a mandatory monitoring procedure that have been implemented. With this continuous improvement process, RCAT subsequently hosted the Perioperative and Anesthetic Adverse Events in Thailand (PAAAd Thai) study in 2015 [7]. The aim of this study was to investigate the incidence of perioperative and anesthesia adverse events, contributing factors, factors minimizing outcomes, and to suggest strategies to avoid specific adverse events.

Methods

The present prospective multicentered study, a part of the PAAAd Thai study, was conducted by the RCAT between January 1 and December 31, 2015. All anesthesiologists and nurse anesthetists in 22 participating hospitals across Thailand were asked to report critical incidents on an anonymous basis.

After being approved by each institutional ethics committee, informed consent was exempted. The specific anesthesia-related adverse events detected during anesthesia and during the 24 h postoperative period were reported by completing a standardized incident reporting form as soon as possible after the occurrence of adverse or undesirable events. These events included pulmonary aspiration, suspected pulmonary embolism, esophageal intubation, endobronchial intubation, oxygen desaturation (<85% or <90% for >3 min), reintubation, difficult intubation (>3 times or >10 min), failed intubation, total spinal block, awareness during general anesthesia, coma/cerebrovascular accident/convulsion, nerve injury,

transfusion mismatch, suspected myocardial infarction/ischemia, severe arrhythmia (such as: atrial fibrillation with rapid ventricular response, second or third degree atrioventricular block, ventricular tachycardia, ventricular fibrillation, bradycardia <40 beats/min), cardiac arrest, death (all causes), suspected malignant hyperthermia, anaphylaxis/anaphylactoid reaction/allergy, drug error, equipment malfunction/failure, suspected emergence delirium, wrong patient/site/surgery. Oxygen desaturation in the present study was defined as SpO₂ below 90% for >3 min or once below 85% as detected by pulse oximetry. The anesthesia profiles, surgical profiles, and narrative description of incidents were also recorded. Details of the present study methodology have been described [7]. All incident record forms and monthly reports of anesthesia statistics were verified by the site manager and sent to the data management unit at the Faculty of Medicine, Chulalongkorn University. Descriptive statistics used for analysis were determined using SPSS for Windows, version 22 (IBM Corp, Armonk, NY, USA). Each critical incident of the first 2,000 incidents was reviewed by a group of reviewers and will be presented in subsequent PAAAd Thai Studies.

Results

Between January 1 and December 31, 2015, some 333,219 patients underwent anesthesia in the 22 participating hospitals. Among these, the main anesthetic techniques used were 216,179 cases of general anesthesia (64.8%), 27,191 cases of general total intravenous anesthesia (8.2%), 15,793 cases of monitored anesthesia care (4.7%), 62,102 cases of spinal anesthesia (18.6%), and 1,895 cases of epidural anesthesia (0.6%).

After screening by the site manager of each hospital and the project manager (SC), 2,206 incident report forms with 3,028 critical incidents were sent to the data management unit. The 22 public hospitals representing all regions of Thailand were recruited as the PAAAd Thai study participants [7]. The age of patients reported varied from 1 day to 97 years with a male:female sex ratio of 1,136:1,050 (52%:48%). **Figures 1 and 2** respectively show the distribution of age and American Society of Anesthesiologists Physical Status (ASA PS) classification of patients in the PAAAd Thai database.

Among 2,206 incident reports, general surgery, orthopedic surgery, neurosurgery, cardiac surgery, and

gynecological surgery accounted for 64.8% of the surgery with critical incidents. Details of the site of surgery or operation are shown in **Table 1**. Monitoring equipment used during anesthesia is shown in **Table 2**.

Information regarding the phase of anesthesia relevant to incident reports and location is shown in **Table 3**. Practitioners of anesthesia during which critical incidents occurred were anesthesiologists (51.9%), nurse anesthetists (44.9%), anesthesia residents (34.3%), nonanesthesia residents (1.1%), surgeons (0.4%), anesthesia nurse trainees (8.5%), and medical students (1.5%). The incidents classified by perioperative periods are shown in **Table 4**. There was a case report of suspected malignant hyperthermia in a university hospital.

The detection of incidents by clinical diagnosis in the database of 2,206 incident reports were in 2,003 cases (96.8%), of which the clinical diagnosis was achieved before in 860 cases (41.5%) and after diagnosis by monitoring equipment in 1,008 cases (48.7%). The diagnosis of incidents was achieved by monitoring alone in 203 cases (9.8%) or clinical skill alone in 135 cases (6.6%).

The immediate and long-term outcomes are shown in **Table 5**. According to the opinions of attending personnel and site manager of each hospitals, contributing factors are shown in **Table 6**, factors minimizing outcomes are shown in **Table 7**, and suggested corrective strategies to avoid the occurrence of incidents are shown in **Table 8**.

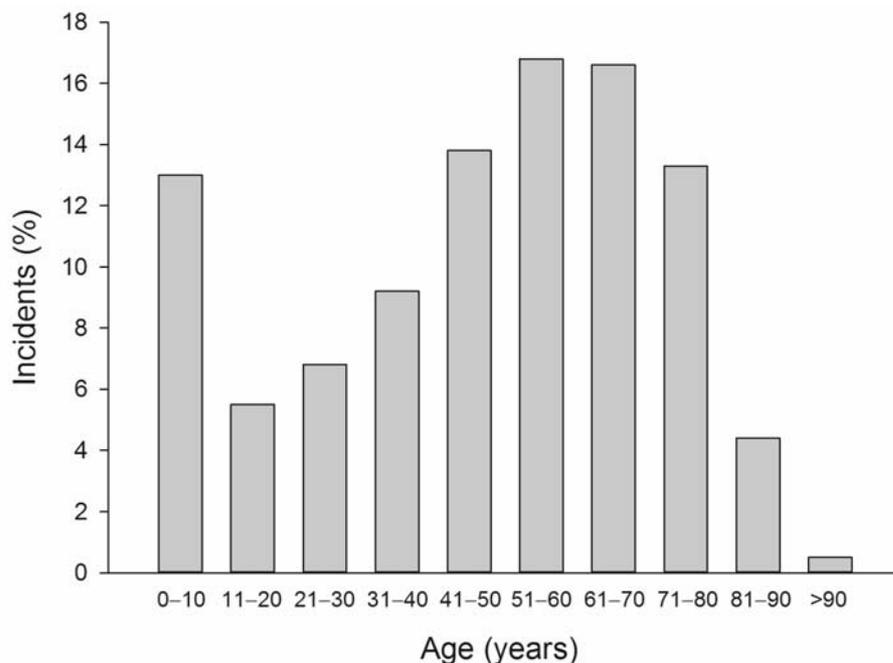


Figure 1. Age distribution of patients in 2,206 incident reports

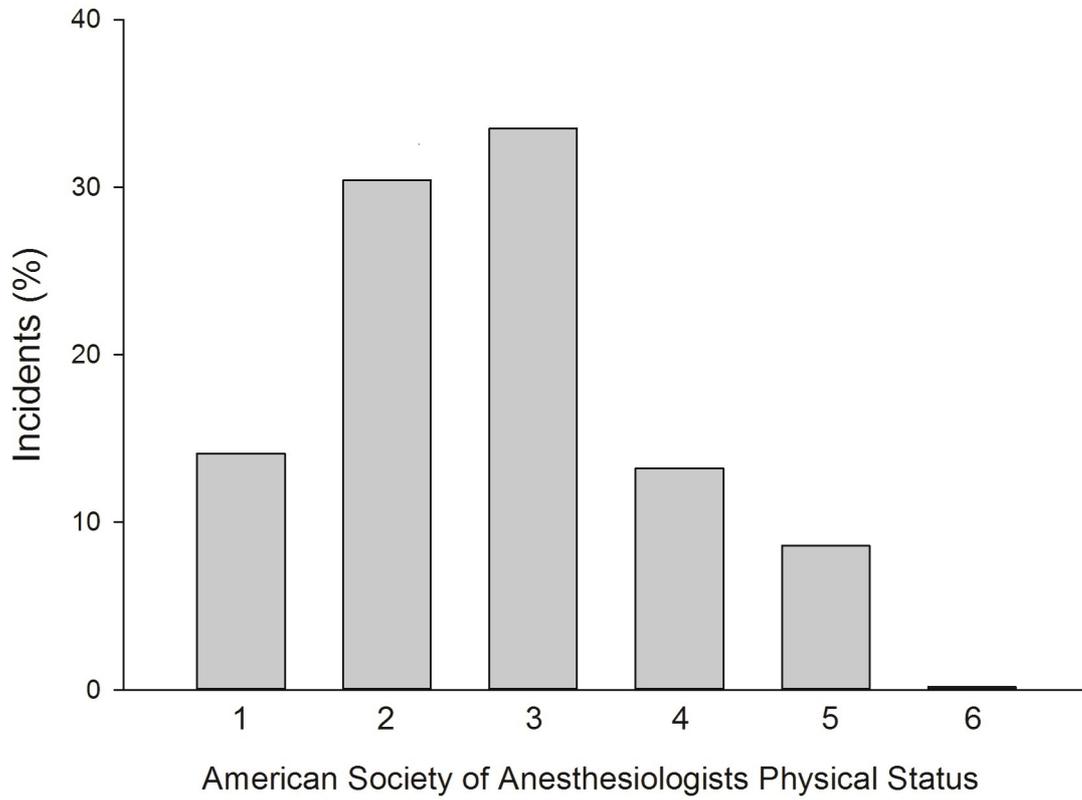


Figure 2. ASA physical status classification of patients in 2,206 incident reports

Table 1. Operation or operative site of surgery in 2,206 incident reports

	n (%)
General surgery	690(31.3)
Orthopedic	267(13.0)
Neurosurgery	168(7.6)
Cardiac	148(6.7)
Gynecological	137(6.2)
Otorhinolaryngological	127(5.8)
Thoracic	117(5.3)
Urological	111(4.9)
Endoscopic	85(3.9)
C-section	74(3.4)
Vascular	71(3.2)
Ophthalmological	69(3.1)
Plastic	47(2.1)
Dental	24(1.1)
Intervention	24(1.1)
Minimally invasive	19(0.9)
Diagnostic	8(0.4)
Electroconvulsive	2(0.1)
Radiotherapy	2(0.1)

Remark: numbers are not mutually exclusive

Table 2. Monitoring equipment used during anesthesia in 2,206 incident reports

Monitoring equipment	n (%)
Pulse oximeter	2188 (99.2)
Electrocardiograph	2180 (98.8)
Sphygmomanometer (noninvasive blood pressure)	2144 (97.2)
Capnometer	1789 (81.8)
Spirometer	1005 (45.6)
End tidal gas analyzer	820 (37.2)
Invasive arterial pressure monitor	531 (24.1)
Thermometer	476 (21.6)
Central venous pressure catheter	402 (18.2)
Oxygen analyzer	391 (17.7)
Pulmonary arterial pressure analyzer	37 (1.7)
Echocardiograph	25 (1.1)
Electroencephalograph	12 (0.5)
Cardiac output monitor	7 (0.3)

Remark: numbers are not mutually exclusive

Table 3. Phase and location of occurrence of incidents (N = 2,206 reports)

	n (%)
Phase	
Preinduction	112 (5.1)
Induction	496 (22.5)
Maintenance	761 (34.5)
Emergence	152 (6.9)
Recovery	224 (10.2)
Postoperative 24 h	381 (17.3)
Location	
Induction room	15 (0.7)
Operating room	1433 (65.0)
Recovery room	235 (14.6)
Intensive care	167 (7.6)
Delivery room	3 (0.1)
Ward	239 (10.8)
Imaging unit	10 (0.5)
During transportation	14 (0.6)
Others (gastrointestinal endoscopy unit, catheterization laboratory, emergency)	6 (0.2)

Remark: numbers are not mutually exclusive

Table 4. Critical incidents classified by perioperative periods for 2,206 incident reports and overall incidence

	Critical incidents (N = 2,206 reports)			Overall Incidence (95% CI) per 10,000
	Operative period n (%)	Postanesthesia care unit n (%)	Postoperative 24 h n (%)	
Pulmonary aspiration	30(1.4)	1(0.1)	2(0.1)	1.36(0.89, 1.82)
Suspected pulmonary embolism	14(0.6)	4(0.2)	1(0.0)	0.51(0.27, 0.75)
Esophageal intubation	184(8.3)	–	–	8.51(7.28, 9.74)
Endobronchial intubation	24(1.1)	–	–	1.11(0.67, 1.55)
Oxygen desaturation	342(15.5)	119(5.4)	17(0.8)	13.95(12.69, 15.00)
Reintubation	63(2.9)	113(5.1)	66(3.0)	11.10(9.70, 12.51)
Difficult intubation	172(7.8)	2(0.1)	–	8.00(6.81, 9.19)
Failed intubation	16(0.7)	–	–	0.74(0.38, 1.10)
Total spinal block	2(0.1)	–	–	0.32(–0.12, 0.77)
Awareness during general anesthesia	–	–	10(0.5)	0.41(0.16, 0.67)
Coma/cerebrovascular accident/convulsion	8(0.4)	11(0.5)	39(1.8)	1.59(1.16, 2.02)
Nerve injury	5(0.2)	1(0.1)	16(0.7)	0.63(0.36, 0.90)
Transfusion mismatch	4(0.2)	3(0.2)	–	0.21(0.05, 0.37)
Suspected myocardial infarction/ischemia	20(0.9)	4(0.2)	14(0.6)	1.02(0.68, 1.36)
Severe arrhythmia	467(21.2)	–	–	14.01(12.74, 15.29)
Cardiac arrest within 24 h	255(11.6)	9(0.4)	272(12.3)	15.58(14.24, 16.91)
Death within 24 h	107(4.9)	5(0.3)	330(15.0)	13.26(12.03, 14.50)
Anaphylaxis/anaphylactoid reaction/allergy	67(3.0)	14(0.6)	1(0.0)	2.37(1.85, 2.89)
Drug error	104(4.7)	1(0.1)	2(0.1)	3.21(2.60, 3.82)
Equipment malfunction/failure	47(2.1)	–	2(0.1)	1.41(1.01, 1.81)
Anesthesia personnel hazard	2(0.1)	15(0.7)	–	0.60(0.34, 0.97)
Suspected emergence delirium	2(0.1)	15(0.7)	–	0.60(0.34, 0.97)
Wrong patient/site/surgery	6(0.3)	–	–	0.18(0.04, 0.32)

Remark: numbers are not mutually exclusive

Table 5. Immediate and long-term (7-day) outcomes for 2,206 incident reports

	n (%)
Immediate outcomes	
Complete recovery	553 (25.1)
Death	432 (19.6)
Major physiological change	326 (14.8)
Respiratory	207 (9.4)
Cardiovascular	91 (4.1)
Neurological	66 (3.0)
Cardiac arrest	261 (11.8)
Unplanned intensive care unit admission	163 (7.4)
Minor physiological change	72 (3.3)
Prolonged emergence	20 (0.9)
Awareness	7 (0.3)
Unplanned hospital admission	5 (0.2)
Other	79 (3.6)
Long-term (7-day) outcomes	
Complete recovery	265 (12.0)
Death	249 (11.3)
Prolonged hospital stay	144 (5.2)
Prolonged ventilator support	132 (6.0)
Disability	6 (0.3)
Vegetative stage	6 (0.3)
Psychic trauma	2 (0.1)
Other	7 (0.3)

Table 6. Factors contributing to the incidents (N = 2,206 reports)

Contributing factors	n (%)
Noncompliance with surgical safety checklists	35 (1.6)
Inappropriate decision	307 (13.9)
Inadequate knowledge	125 (5.7)
Inexperience	630 (28.6)
Haste	188 (8.5)
Fatigue	11 (0.5)
Inadequate personnel	24 (1.1)
Communication defect	86 (3.9)
Not familiar with environment	6 (0.3)
Emergency condition	418 (18.9)
Inadequate preanesthetic evaluation	333 (15.1)
Inadequate preanesthetic preparation	116 (5.3)
Inadequate equipment	35 (1.6)
Inefficient equipment/monitoring	55 (2.5)
Monitor not available	8 (0.4)
Error in drug label	29 (1.3)
No recovery room	4 (0.2)
Blood bank problems	21 (1.0)

Table 7. Factors minimizing incidents in 2,206 incident reports

Factors	n (%)
Compliance with surgical safety checklists	105 (4.8)
Having experience	995 (45.1)
Experienced assistant	736 (33.4)
Vigilance	1150 (52.1)
Adequate personnel	32 (1.5)
Effective supervision	129 (5.8)
Effective communication	186 (8.4)
Improvement of training	75 (3.4)
Adequate equipment	83 (3.8)
Adequate maintenance	44 (2.0)
Equipment check up	57 (2.6)
Adequate monitoring equipment	85 (3.9)
Comply to practice guidelines	189 (8.6)
Other	58 (2.6)

Table 8. Suggested corrective strategy for prevention of occurrence of incidents (N = 2,206 reports)

Factors	n (%)
Compliance with surgical safety checklists	114 (5.2)
Compliance with guidelines	638 (28.9)
Additional training	502 (22.8)
More manpower	87 (3.9)
Improvement of supervision	497 (22.5)
Improvement of communication	209 (9.5)
More equipment	76 (3.4)
Equipment maintenance	59 (2.7)
Quality assurance activity	452 (20.5)
Good referral system	33 (1.5)
Other	38 (1.7)

Discussion

The PAA Thai study was conducted using incident reporting as a tool to improve the safety and quality of anesthesia in Thailand. An incident reporting system can be a powerful tool for complex systems such as anesthesiology, and has been of proven benefit in aviation, nuclear power plants, and the oil industry [8]. It is based on the potential to learn from critical events [9, 10]. In 2005, the RCAT launched the Thai Anesthesia Incidents Study (THAI Study), a registry documenting the incidence of anesthesia-related adverse events [3, 4]. In 2007, the RCAT initiated the Thai Anesthesia Incidents Monitoring Study (Thai AIMS) to investigate the occurrence of anesthesia-related complications on a voluntary and anonymous basis in an attempt to improve clinical practice

guidelines, monitoring techniques, and education [5, 6, 11]. The present PAA Thai study revealed the current status of surgery, anesthesia, and their adverse events after a decade of continuing safety, and quality improvement in a developing country.

During the 12-month period of the present study, 2,206 incident reports of 3,028 incidents were screened by the site manager and project manager and sent to the data management center. The first 2,000 incidents reported were reviewed by at least 3 senior anesthesiologists to investigate contributing factors, factors minimizing outcomes, and strategies suggested using the model developed by the Australian Anesthesia Incident Monitoring Study [12, 13]. In our multicentered study, a total of 333,219 anesthetic procedures were performed with 64.8% of general

anesthesia, 8.2% of general anesthesia total intravenous anesthesia (GATIVA), 4.7% of monitored anesthesia care (MAC), 18.6% of spinal anesthesia, and 0.6% of epidural anesthesia as consistent with a previous study [4]. The incidence of specific adverse events was calculated by using appropriate denominators. In Thailand, all regional anesthetic procedures are performed exclusively by physicians or certified anesthesiologists. Nurse anesthetists are legally allowed to performed general anesthesia in public hospitals. Trainees such as residents, anesthesia nurse students, and medical students can provide anesthesia under supervision of attending personnel. Therefore, the status of the practitioner and type of hospital such as “university”, or “nonuniversity” may affect specific outcomes. This will be analyzed and reported in subsequent articles.

Compared with our previous incident report, patients in the PAAd Thai Study were in general older than those of the Thai AIMS. The age of two-thirds of patients in the present study was between 41 and 80 years, while the age of 70% of patients in the Thai AIMS were between 31 and 60 years. The possible explanations are that the Thai population is aging as a society, and patients with older age have better accessibility to surgery and possibility experience more critical incidents. About 13% of perianesthetic adverse events occurred in patients <10 years old and about 18% in patients >70 years old (**Figure 1**). Patients at age extremes, that is pediatric and geriatric patients, generally have a higher risk of adverse events [14, 15].

Compared with the female:male sex ratio of 5.3:4.7 in the THAI Study that represented patients undergoing surgery in Thailand, the female:male sex ratio of patients in the PAAd Thai study was 4.8:5.2. The more frequent incidence of critical events that occurred in male patients was similar to that found in previous studies [6]. The proportion of patients in the PAAd Thai study was consistent with the Thai AIMS because both studies were confined exclusively to patients who experienced critical incidents. More than half of incident reports occurred in ASA PS groups 3, 4, and 5. However, critical incidents also occurred in patients with normal or mild systemic diseases (ASA PS of 1 and 2) comprising 44.5% (**Figure 2**). Therefore, attending anesthesia personnel should remain vigilant for adverse events in patients receiving surgery with no underlying disease.

The common operative sites or types of surgery reported to have critical incidents in the present study (**Table 1**) were consistent with the Thai AIMS [6]. Therefore, neurological, otorhinolaryngological, and cardiothoracic surgeries posed a high risk for occurrence of critical incidents. Adverse events occurred frequently in emergency situations (36.5%).

The objective of monitoring is to augment clinical observation for the attending anesthesia practitioner and to help decision making during the administration of anesthesia and other treatments. The present study showed that pulse oximetry, electrocardiography, and NIBP were most common monitoring used during anesthesia (**Table 2**). This finding showed that the RCAT was successful in implementing clinical practice guidelines regarding monitoring with pulse oximetry since 2007. Use of pulse oximetry was changed to be mandatory by the RCAT one year before the World Health Organization campaign for global oximetry in 2008. The proportion of capnometer use during general anesthesia in the present study was high because of their increased availability in medical institutions. The results may support the feasibility of the RCAT policy in using a capnometer as mandatory monitoring equipment during general anesthesia.

Among the incident reports, common phases of anesthesia when critical incidents occurred were the induction and the maintenance phases (**Table 3**). The common locations where incidents occurred were in the operating room, ward, and postanesthesia care unit. In the Australian Incident Monitoring Study, the common sites where critical incidents occurred were the operating theater (75%), induction room (10%), and recovery room (6%) [13]. A possible explanation for the differences is that separate induction rooms are rarely designated in Thai hospitals. The phases and locations of incidents in the present study were similar to those found in our previous study [6]. Therefore, anesthetic personnel should pay attention during the preanesthetic period, such as during preanesthetic evaluation and preparation. There was empirical evidence that use of a preinduction checklist improved information exchange and perception of safety in the anesthesia team [16].

About half of the perianesthetic adverse events that occurred within 24 h were respiratory system complications such as oxygen desaturation, reintubation, suspected pulmonary aspiration, and esophageal intubation (**Table 4**). Analysis of these common critical events will be subsequently published

to identify corrective strategies that can be suggested. The incidence of difficulty with intubation in the present study was 8.0:10,000 revealing a dramatic decrease from that observed in our previous study. In 2006, our registry showed that the incidence of difficult intubation was 22.5:10,000 [4] and over part of a meta-analysis that the modified Mallampati score was inadequate as a single test for difficult laryngoscopy [13, 17]. Subsequent study regarding esophageal intubation will consider appropriateness and feasibility of using capnometry as mandatory monitoring for general anesthesia in a national context in Thailand. The incidence of 24 h perianesthetic cardiac arrest and mortality (all causes) in the PAAAd Thai Study were 15.5 and 13.2 per 10,000 respectively, which were lower than those in the THAI Study, which found incidence rates of 30.8 and 28.3:10,000 respectively [4]. These dramatic decreases showed substantial safety improvement of anesthesia and surgery in government hospitals in Thailand. There were several continuous quality improvement activities, such as improvement of clinical practice guidelines according to national evidence, and improvement in monitoring, training, and an increase in the number of anesthesia practitioners in the government sector [18-20]. Like the Thai AIMS, common critical incidents in the recovery room were oxygen desaturation and reintubation. Sun et al. [21] found that hypoxemia was common and prolonged in patients recovering from surgery. The present study confirmed that the incidence of malignant hyperthermia in Thailand was between 1:150,000 and 1:200,000 patients receiving general anesthesia [22].

The immediate outcomes were death, major physiological change; including respiratory, cardiovascular, and neurological problems; and unplanned intensive care unit admission. However,

one-quarter of incident reports experienced complete recovery. For late outcomes within 7 days, the common outcomes were death, prolonged ventilator support, and prolonged hospital stay, while 12% of reports were of patients with complete recovery (Table 5).

A model of anesthesia-related adverse events comprised of contributing factors, factors minimizing incidents, and suggested preventive strategies is shown in Figure 3.

The current PAAAd Thai incident reporting study resembles story telling or a collection of organizational experience. The lessons learnt can be used locally in hospitals and at a national level, and include improvement of clinical practice guidelines, monitoring, improvement of system factors, and education including both knowledge and anesthesia nontechnical skill. For example, the use of a capnometer should be considered in a substudy regarding esophageal intubation. Some common or rare, but serious critical incidents should be selected as topics for simulation training, and study of anesthesia nontechnical skills in residency and nurse anesthetist training.

The present study has some limitations. First, incident reports were on an anonymous basis, some soft outcomes or incidents might be under-estimated. However, we organized several meetings and workshops before the participating hospitals agreed to participate in this multicenter project in an attempt to minimize this problem. Second, there were differences between the PAAAd Thai study 2015 and the Thai AIMS 2007, such as the 12 month vs 6 months period; and 22 hospitals vs 51 hospitals. Most of the hospitals providing incident reports were the same and familiar with incident reporting system and its definition as declared by the Royal College of Anesthesiologists of Thailand. Third, uncertainty remains, especially of reporting bias. We did not know if: all incidents that

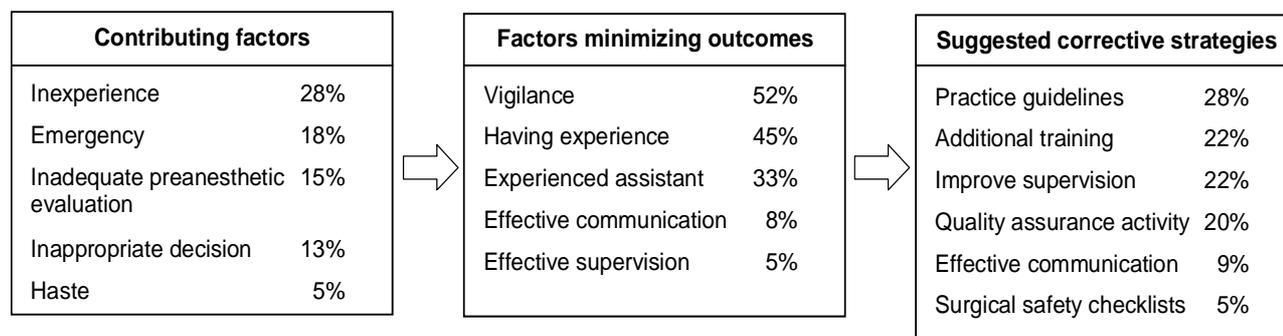


Figure 3. Model of anesthesia related adverse events in the Perioperative and Anesthetic Adverse Events in Thailand (PAAAd Thai) study

happened have been reported, which were reported or were not reported, how many incidents have not been reported. However, we did an interim analysis after 6 months of study and compared findings with those at the end of 12 months of data collection. We found the incidence of hard outcomes such as cardiac arrest within 24 h, death within 24 h, esophageal intubation, and difficult intubation were all comparable.

Conclusion

In the past decade, the incidence of most anesthetic adverse events decreased in Thailand. The dramatic reduction in the perioperative cardiac arrest and difficult intubations displays marked improvement in anesthetic care. The majority of adverse events are respiratory and cardiovascular complications. However, in the postanesthesia care unit, oxygen desaturation, and reintubation are leading causes.

The common contributing factors for critical incidents were inexperience, emergency conditions, inadequate preanesthetic evaluation and preparation, and inappropriate decision making. By contrast, the factors minimizing incidents were vigilance and advanced experience. Suggested corrective strategies are improvement in compliance with practice guidelines, quality assurance activity, continuing education, and improvement of supervision.

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Conflict of interest statement

The authors have no conflict of interest to declare.

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