Original Article

The Perioperative and Anesthetic Adverse Events in Thailand (PAAd Thai) Study of Anesthetic Equipment Malfunction or Failure: An Analysis of 2,206 Incident Reports

Panaratana Ratanasuwan MD[1], Wimonrat Sriraj MD[1], Yodying Punjasawadwong MD[2], Jaroonpong Choorat MD[3], Somrat Charuluxananan MD[4], Thanist Pravitharangul MD[5]

[1] Department of Anesthesiology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand

[2] Department of Anesthesiology, Faculty of Medicine, Chiang Mai University, Chiang Mai, Thailand

[3] Department of Anesthesiology, Sunpasitthiprasong Hospital, Ubon Ratchathani, Thailand

[4] Department of Anesthesiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

[5] Department of Anesthesiology, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Background: Anesthesia equipment problems may contribute to anesthesia mortality and morbidity. The Royal College of Anesthesiologists of Thailand initiated a multicentered incident reporting study namely the Perioperative and Anesthetic Adverse Events in Thailand (PAAd Thai) Study to investigate perioperative complications including equipment malfunction or failure.

Materials and Methods: The present report was a descriptive prospective study. After the Institutional Ethical approval with informed consent was waived, the case record form comprising structured and narrative information parts was requested to be filled within 24 hours of occurrence of anesthesia equipment malfunction or failure in 22 large government hospitals across Thailand between January and December 2015. Three senior anesthesiologists reviewed the incident reports. Any discrepancy was discussed to achieve a consensus. Descriptive statistics were used for analysis.

Results: Out of 2,206 incident reports, there were 47 (2.1%) equipment malfunction or failure involving anesthetic machine (36.0%), anesthetic circuit (27.6%), laryngoscope (17.0%) and monitoring (12.7%) in operating theatre (97.8%), pediatric anesthesia (19.1%), and emergency condition (21.2%). Diagnoses of incidents was either clinical detection (82.9%) or detection by monitoring equipment (48.9%). Outcomes of incidents were trivial with full recovery. The incidents were considered as results from human factor (38.3%), preventable (46.8%), and might be prevented with surgical safety checklists (34.0%).

Conclusion: Equipment malfunction or failure incidents were unusual and did not lead to serious consequence. Common contributing factors were ineffective equipment, non-adherence to surgical checklists, haste, and inexperience of performers. Factors to minimize the incidents were equipment checking, having experience, and comply to surgical checklists. Quality assurance activity, standard and regular equipment maintenance, adherence to surgical checklists, and additional training were suggested as corrective measures.

Keywords: Anesthesia, Complications, Equipment malfunction, Equipment failure, Human factors, Surgical checklist

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Maintaining patient safety has been accepted as a crucial part of anesthesia practice. There are several methods for obtaining data regarding perioperative and anesthesia-related adverse events. Previously, the Royal College of Anesthesiologists of Thailand (RCAT) initiated a registry of anesthesia incidents among 22 hospitals across Thailand to investigate incidences of various anesthesia-related complications and their contributing factors, namely the Thai Anesthesia Incident Study (THAI Study)[1,2]. The incidence of equipment malfunction or failure in the THAI Study (2005) was 3.4 (95% confidence interval [CI] 2.5 to 4.3): 10,000. Subsequently in 2007, the Thai Anesthesia Incident Monitoring Study, an incident reporting study (Thai AIMS) revealed a proportion of 5% of a total number of 1996 incidents was equipment failure or malfunction[3,4]. Several

Correspondence to:

Sriraj W.

Department of Anesthesiology, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand.

Phone: +66-43-348390, Fax: +66-43-348390 ext. 405

Email: wimsri@kku.ac.th

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safety and quality improvement process have been launched by the RCAT for a decade resulting in improvement of monitoring of anesthesia. The present study, the Perioperative and Anesthetic Adverse Events in Thailand (PAAd Thai) Study[5,6] aimed to investigate the contributing factors, minimizing factors, and suggested preventive measures for equipment malfunction or failure among 22 large government hospitals across the Kingdom of Thailand.

Materials and Methods

The present study was part of the PAAd Thai Study hosted by the RCAT, which was approved by the Institutional Review Board Committees and the informed consent was waived due to it observational descriptive research design[5]. Eight university hospitals and 14 service-based hospitals from all regions of Thailand participated in the study. The anesthesia providers of these hospitals were asked to report interesting incidents on voluntary and anonymous basis. The detected specific adverse events of interest during anesthesia and within 24 hours postoperatively were recorded in a structured incident report form together with open-ended narrative explanation of the occurrence. The adverse events of interest were pulmonary aspiration, esophageal intubation, oxygen desaturation as SpO_2 of 85% or less or 90% or less for more than three minutes, re-intubation, difficult intubation, intraoperative awareness, equipment malfunction and failure. Definitions of equipment malfunction or failure were defined as (A) true equipment failure where the equipment malfunction or fail to perform their tasks, and (B) equipment problems because of human errors or failure to check is involved. The authors did not include surgical equipment or technical problems with anesthetic or surgical procedures as described by Fasting and Gisvold[6]. A site manager of each hospital reviewed the incident reports and sent a monthly report of anesthesia service to the data management center at Chulalongkorn University. Three senior anesthesiologists reviewed the incidents. Any discrepancy was discussed to achieve a consensus. Descriptive statistics were used for data analyses.

Results

There were 48 cases of incident reports of equipment malfunction or failure sent to the data management center. One case was excluded because of its irrelevance to the definition, which was a pediatric patient that received general anesthesia with a surgical equipment malfunction. The ophthalmic surgery was cancelled after 40 minutes of anesthesia due to laser equipment malfunction. Therefore, this left 47 patients with anesthesia equipment malfunction or failure. These patients were American Society of Anesthesiologists physical status I, II, and III, respectively with 13 cases (27.6%), 17 cases (36.2%), and 17 cases (36.2%), respectively. Twenty incidents (42.5%), 27 incidents (57.4%), and 10 incidents (21.2%) occurred in university hospitals, service-based hospital, and emergency condition, respectively. There were 16 cases (34.0%), eight cases (17.0%), five cases (10.6%), five cases (10.6%), four cases (8.5%), four cases (8.5%), three cases (6.4%), and two cases (4.2%) experiencing equipment malfunction or failure in specialties of surgery, including general, obstetric-gynecological, orthopedic, neurosurgical, ear-nose-throat, cardiothoracic, plastic, and ophthalmic, respectively.

Equipment malfunction or failure occurred in patients across all age groups. Nine cases (19.1%) were pediatric patients with age of not more than 15 years old.

Among 47 occurrences of equipment malfunction or failure, 46 cases (97.8%) occurred in operating theatre and one case (2.1%) occurred during the transfer process. Six cases (12.7%), 17 cases (36.1%), and 21 cases (44.6%) occurred during preinduction, induction, and maintenance periods. Types of equipment related to equipment malfunction or failure were 16 incidents of the anesthetic machines (34.0%), 13 incidents in part of an anesthetic circuit (27.6%), eight incidents in the laryngoscopes (17.0%), and six incidents in the monitoring equipment (12.7%). Details of types of equipment and phases of anesthesia when the incidents occurred are shown in Table 1. There were 14 incidents that equipment was changed or substituted with new ones for safety. The equipment incidents necessitating changes or substitution included six incidents (12.7%) of laryngoscopes, four incidents (8.5%) of monitoring equipment, two incidents (4.3%) of anesthetic machines, and two incidents (4.3%) of anesthetic circuits. Details of equipment malfunction or failure necessitating changes or substitution with new equipment are also shown in Table 1.

Among eight incidents are related to laryngoscope, all incidents occurred with failure of lighting although all these laryngoscopes were checked in preanesthetic period. Six incidents (75%) necessitated changes or substitution with a new laryngoscope. There were 16 incidents related to anesthetic machines of which

Table 1. Phases, types and equipment malfunction or failure necessitating changes of equipments (n=47)

	n (%)
Types of equipments	
Anesthetic machine	16 (36.0)
Part of anesthetic circuit	13 (27.6)
Laryngoscope	8 (17.0)
Monitoring equipment	6 (12.7)
Ventilator	4 (8.5)
Vaporizer	4 (8.5)
Difficult airway adjunct	1 (2.1)
Phases	
Preinduction	6 (12.7)
Induction	17 (36.1)
Maintenance	21 (44.6)
Emergence	2 (4.3)
Postrecovery	1 (2.1)
Equipment incidents necessitating change/substitution of equipment	
Laryngoscope	6 (12.7)
Monitoring equipment	4 (8.5)
Anesthetic machine	2 (4.3)
Anesthetic circuit	2 (4.3)
Ventilator	1 (2.1)
Vaporizer	1 (2.1)

Table 2. Problems related to equipments

Equipment	Sites of problem	Frequency; n (%)
Anesthetic machine (n=16)	Leakage	4 (25.0)
	Stopped	3 (18.7)
	Malfunction	3 (18.7)
	Ventilation failure	3 (18.7)
	Disconnection (connector)	1 (6.2)
	Misconnection (scavenging)	1 (6.2)
	Common gas outlet	1 (6.2)
Anesthetic circuit (n=13)	Carbondioxide absorber	3 (6.4)
	Circuit leakage	2 (4.3)
	Vaporizer leakage	2 (4.3)
	Disconnection	2 (4.3)
	Misconnection	1 (2.1)
	No reservoir bag (dilution of gas)	1 (2.1)
	Scavenging tube	1 (2.1)
	Obstruction of expiratory valve	1 (2.1)
Monitor equipments (n=6)	Noninvasive blood pressure	3 (50.0)
	Pulse oximetry	2 (33.3)
	Electrocardiography	1 (16.6)

four incidents (25.0%) were leakage, three incidents (18.7%) were machine failure or non-function, three incidents (18.7%) were abnormal function, three incidents (18.7%) were ventilator failure, and other incidents were related to disconnection, misconnection.

There were six incidents regarding monitoring equipment malfunction or failure including three incidents (50%) of blood pressure monitoring equipment malfunction, two incidents (33.3%) of pulse oximeter malfunction, and one incident (16.6%) of malfunctioning electrocardiography device. Two-thirds (66.6%) of these incidents required changes to alternative equipment.

Among 13 incidents of errors related to any part of anesthetic circuit, three incidents (23.0%), two incidents (15.4%), two incidents (15.4%), and two incidents (15.4%) were related to problems of carbon-dioxide absorber canister, leakage of circuit, disconnection of circuit, and leakage at vaporizer site, respectively. Table 2 summarizes the problems related to equipment incidents.

There were four incidents of vaporizer-related malfunction or failure. Of which, three incidents (75%) occurred as leakage of anesthetic system and two incidents (50%) could be resolved by adjustment of position of vaporizer.

There were four incidents of ventilator malfunction, of which two incidents could be resolved by minor adjustments. Another incident necessitated change of equipment and the incidents had to be manual ventilation by anesthesia provider.

Performers of anesthesia during the equipment malfunction or failure were nurse anesthetists for 18 incidents (38.2%), anesthesiologists for 10 incidents (21.2%), residents for 12 incidents (25.5%), and anesthesia nurse trainees for seven incidents (14.9%). The personnel who detected the incidents were nurse anesthetists in 24 incidents (51.0%), anesthesiologists in 16 incidents (34.0%), and residents in six incidents (12.7%).

Monitoring equipment that firstly detected or alarmed warning for any incidents were pulse oximetry in 10 incidents (21.2%), alarm in seven incidents (14.8%), non-invasive blood pressure monitoring in two incidents (4.3%), capnography in two incidents (4.3%), and electrocardiogram in one incident (2.1%), respectively.

Detection or diagnosis of equipment malfunction or failure were as following, clinical detection only (51.0%), clinical before monitoring detection

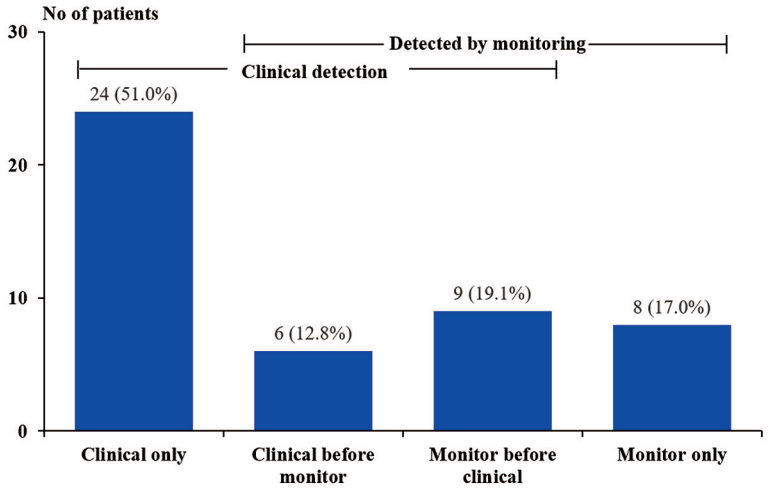

Figure 1. Clinical or monitoring detection of equipment malfunction or failure incidents (n=47).

Table 3. Contributing factors, factors to minimize incident and suggested corrective strategies (n=47)

	n (%)
Contributing factors	
Ineffective equipment	17 (36.1)
Surgical checklists not complied	12 (25.5)
Haste	7 (14.9)
Inexperience	6 (12.8)
Ineffective monitor	4 (8.5)
Inadequate preanesthetic preparation	3 (6.4)
Emergency	2 (4.3)
Lack of knowledge	1 (2.1)
Factors to minimize incident	
Equipment checking	22 (46.8)
Having experience	15 (31.9)
Surgical checklists adherence	11 (23.4)
Experienced assistant	8 (17.0)
Suggested corrective strategies	
Equipment maintenance	21 (44.6)
Quality assurance activity	21 (44.6)
Surgical checklists	12 (25.5)
More equipment	8 (17.0)
Clinical practice guidelines	8 (17.0)
Additional training	8 (17.0)
Improvement of supervision	4 (8.5)

Data are not mutually exclusive

(12.8%), clinical diagnosis after monitor detection (19.1%), and monitoring detection only (17.0%). Figure 1 shows the details of detection of the equipment-related incidents.

Among the 47 incidents of equipment malfunction or failure, 33 incidents (70.2%) developed no consequence, three incidents (6.4%) developed minor physiologic changes such as changes of blood pressure or heart rate, and five incidents (10.6%) had major physiologic changes such as hypoxia or major cardiovascular deterioration with full recovery.

After reviewing of incidents, the contributing factors, factors to minimize incidents, and suggested corrective strategies are shown in Table 3. The equipment malfunction or reports were considered as spontaneous or inevitable occurrence, preventable, human factor, and be able to be prevented by completion of surgical safety checklists in 25 incidents (53.2%), 22 incidents (46.8%), 18 incidents (38.3%), and 16 incidents (34.0%), respectively.

Discussion

Forty-seven incidents of equipment malfunction or failure were analyzed. These account for the incidence of 1.41 (95% CI 1.01 to 1.81): 10,000[7] of the PAAd Thai Study and considered as rare. These results were similar to those of the previous studies[2,6,8,9]. All the incidents occurred in patients receiving general anesthesia, which was in accordance with a study of Fasting and Grivoid that equipment malfunction or failure occurred more frequently in general anesthesia than regional anesthesia[6]. In the present study, equipment malfunction or failure did not confine to the American Society of Anesthesiologists (ASA) physical status of patients, types of hospitals, or emergency condition. The

common specialties of surgery which the incidents occurred such as general surgery, orthopedic surgery, obstetric & gynecological surgery, and neurosurgery were also similar to the Norwegian data[6]. One-fifth of incidents occurred in emergency condition and pediatric patients. The incidence of equipment malfunction or failure occurred in pediatric patients receiving anesthesia was 4.3:10,000[10], which was higher than an average incidence among all age groups in the authors previous study[7]. However, the proportion of equipment malfunction or failure in the Australian Incidents Monitoring Study (AIMS) was 9%, which was higher than proportion of 5% in Thai AIMS[4,11].

Most incidents (97.8%) occurred in the operating theatre while one case developed oxygen desaturation during transfer from post anesthesia care unit to intensive care unit because of mismatching of a connector to a mobile ventilator. The patient received ventilatory support manually via ambu-bag with oxygen. The desaturation was fully recovered during the transfer process. The ASA closed claims also revealed that failure supplemental oxygen delivery occasionally occurred outside the operating theatre and involved misuse of tubing or supply tank[12]. Most common phases of equipment-related incidents were induction and maintenance phases while six incidents (12.7%) occurred in the preinduction phase, which was comparable to the THAI Study[13].

Types of equipment related to malfunction or failure were anesthetic machines, anesthetic circuits, laryngoscopes, monitoring equipment and vaporizers, respectively. These incidents were in accordance with common equipment malfunction in THAI registry study[13] and Thai AIMS incident report[14].

Among vaporizer problems, the present study showed no failure to turn on the vaporizer and no failure to notice that the vaporizer was empty that might cause light anesthesia or intraoperative awareness[12]. In the present study, two incidents related to vaporizer were misfit of vaporizers at the back bar of the anesthetic machine. Leak test was not usually performed after replacing a vaporizer as that preanesthetic machine checking might not be able to detect leakage in some occasions. One incident of vaporizer malfunction could be detected by end tidal anesthetic agent analyzer by showing high concentration of volatile anesthetic. The anesthesia provider adjusted the level of anesthesia by the monitor and clinical setting. With vigilance and monitoring of end-tidal, anesthetics can detect most vaporizer problems[15], the current standard for basic monitoring does not require monitoring of anesthetic agents.

The present study also emphasized on satisfactory substitute or spare when equipment was suddenly found to be malfunctioning or failed. The common equipment needing preparedness to change for a new one were laryngoscopes, monitoring equipment, anesthetic machines, and anesthetic circuits.

The performer of anesthesia related to equipment malfunction were nurse anesthetists, anesthesia residents, anesthesiologists and anesthesia nurse trainees. The detectors of incidents were nurse anesthetists in half of occurrences.

Among 47 incidents, 39 incidents (82.9%) were diagnosed by clinical detection, while 23 incidents (48.9%) were diagnosed with monitoring or alarm. Pulse oximetry alarming for desaturation was the most common monitoring that warned anesthesia providers of suspected incidents.

Most of the incidents did not lead to serious adverse outcomes. Only one-tenth of incidents caused major physiologic changes such as oxygen desaturation or major cardiovascular changes, which were fully resolved in all cases. The ASA closed claims project revealed that anesthesia gas delivery claims decreased over time from 4% of claims from the 1970s, 3% from the 1980s, 1% from the 1990s and 1% between 2000 and 2011 and adverse outcomes were also less severe than earlier claims[12]. In the present study, nearly half of incidents were considered as preventable. Human errors or misuse of equipment have been shown to be common causes than actual equipment failure themselves[16]. In the present study, human factors were related to one-third of all incidents, and most of these involved anesthetic machines and circuits. Completion of preanesthetic machine checking was also considered for prevention of equipment malfunction or failure in one-third of incidents. The main contributing factors were ineffective equipment, surgical checklists not complied, haste, and inexperience of performers. Common factors to minimize these issues were completeness of equipment checking, adherence to surgical checklist, and having experiences. Main suggested corrective strategies were equipment maintenance, quality assurance activity, surgical checklists, more equipment, and additional training.

There were several limitations of the present study. 1) The number of the incidents might be underestimated. However, the rarity of equipment-related incidents made it difficult to study prospectively. Voluntary incident reporting was an

appropriate source of data among hospitals that were familiar to this reporting system. 2) The present study was a retrospective analysis of prospective collection of incident reports without randomization. All participating hospitals were asked to report in anonymous fashion with no blame culture. 3) There might be variation of types and number of anesthetic equipment in each hospital. However, the participating hospitals were confined to university and large tertiary hospitals.

Conclusion

Ineffective equipment, non-adherence to surgical safety checklist, haste, and inexperience were the major contributing factors to equipment failure or malfunctions. Factor to minimize equipment incidents were preanesthetic equipment checking, having experience, and compliance to surgical safety checklists. The suggested corrective strategies were equipment maintenance, quality assurance activity, compliance to surgical checklists, and training regarding equipment.

What is already known on this topic?

Anesthesia equipment have been designed to minimize problems caused by human errors. When equipment malfunction or failure occurs, immediate corrective measures should be implemented. A complete set of back-up equipment should be readily available.

What this study adds?

Effective equipment and maintenance of equipment are crucial. Compliance to surgical safety checklists and preanesthetic equipment checking can minimize the incidents. Suggested corrective measures are quality improvement activity, more equipment, and additional training.

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Conflicts of interest

The authors declare no conflict of interest.

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