

Original article

Drug errors from the Thai Anesthesia Incidents Monitoring Study: analysis of 1,996 incident reports

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Background: The Royal College of Anesthesiologists of Thailand arranged the Thai Anesthesia Incidents Monitoring Study (Thai AIMS) to investigate the clinical course, outcome, contributing factors, and suggested preventive strategies for anesthesia related adverse events including drug errors.

Methods: As part of the Thai AIMS, perioperative anesthesia incident reports of adverse events were collected on an anonymous and voluntary basis from 51 participating hospitals across Thailand between January 1 and June 30, 2007. Three anesthesiologists reviewed relevant data of drug error incidents. A descriptive statistics was used.

Results: Among 1,996 incident reports of the Thai AIMS database, there were 82 incidents of drug errors (4.1%). Most of drug errors incidents occurred in maintenance phase (57.3%), general anesthesia (87.8%), and in the operation theatre (91.5%). One-fifth of incidents occurred under emergency condition (95%). Common anesthetic drugs involved were nondepolarizing neuromuscular blocking agent (23.1%), opioids (21.9%), antibiotics (17.1%), succinyl choline (7.3%), and induction agents (6.1%). Giving the wrong drug (35.4%), overdosage of drug (32.9%), problems with labeling (14.6%), and wrong concentration (9.8%) were the most common types of drug errors. Of the 25 substitutions with 14 syringe swap (17.1%) and six-ampule swap (7.3%), 60% involved a different pharmaceutical class of drug. Only 10.9% of incidents resulted in intubation, mechanical ventilation, or unplanned admission to intensive care unit. Seventy-nine point two percent were considered as preventable and 39% were due to system error. Haste (42.7%) was considered as the most common contributing factors while vigilance (72%) and having experience (30.5%) were considered as common factors minimizing medication errors.

Conclusion: Practice guidelines especially using of class specific color labeling, quality assurance activity, improvement of communication, and training were suggested preventive strategies.

Keywords: Adverse event, anesthesia, complication, drug error, medication error, substitution

Patient safety has received increased attention in the last few decades. Incident reporting is now widely accepted as one of the techniques used to improve patient outcome and maintain patient safety at a particular standard level [1-5]. It can be used to assess latent and active human errors. In 2003, the Royal College of Anesthesiologists of Thailand

(RCAT) initiated the Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes, as a registry of all consecutive anesthetics in 20 hospitals, to study incidences of anesthesia related complications [6, 7]. During the 18 months period, analyses of parts of the database of 200,000 anesthetics led to 32 sub-studies providing the baseline incidences of anesthetic adverse outcomes and contributing factors for quality improvement. However, it was limited to patients in university hospitals and general hospitals. Because of this, together with the National Research Council of Thailand, the Thai Joint Commission on Hospital

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Accreditation, and RCAT decided to use incident reporting to identify and analyze anesthesia related incidents from 51 hospitals from all regions of Thailand, namely the Thai Anesthesia Incident Monitoring Study (Thai AIMS).

Latent and active human errors are quite common among anesthesiologists because intravenous administration of anesthesia during surgery is not only a complex process but also a task commonly done under stress and haste conditions over a long period of time [8]. Errors are more prominent compared to other specialties because the drugs are usually administered parenterally [9]. As a part of Thai AIMS, this study aimed to investigate the characteristics, outcomes, contributing factors, and suggested corrective strategies for drug errors during anesthesia practice in 51 hospitals across Thailand.

Methods

The present prospective multicentered study, a part of the Thai Anesthesia Incident Monitoring Study (Thai AIMS), was conducted by the RCAT between January 1 and June 30, 2007. All anesthesiologists and nurse anesthetists in 51 hospitals ranging from district (community) hospitals to tertiary hospitals across Thailand, were invited to report the critical incidents on an anonymous and voluntary basis [10].

After being approved by institutional ethical committee, the specific anesthesia related adverse events detected during anesthesia and during 24 hours postoperative period were reported by filling out a standardized incident reporting form [10] as soon as possible after the adverse or undesirable event. These included pulmonary aspiration, pulmonary embolism, esophageal intubation, endobronchial intubation, oxygen desaturation, re-intubation, difficult intubation, failed intubation, total spinal block, awareness during general anesthesia, coma/cerebro-vascular accident/convulsion, nerve injuries, transfusion mismatch, suspected myocardial infarction/ischemia, cardiac arrest, death, suspected malignant hyperthermia, anaphylaxis, drug error, equipment malfunction, and cardiac arrhythmia requiring treatment. The surgical profiles, anesthesia profiles and a narrative of incidents were also recorded. Details of the present study methodology have been described [10]. All forms were sent to data management unit at Chulalongkorn University. The descriptive statistics (frequency tables with number and percentage) were used to analyze data by using SPSS for Windows, version 12. All

critical incidents of drug error were reviewed by three senior anesthesiologists. Discrepancies among the three members were resolved by discussion.

Results

Out of a total of 1,996 incident report forms, there were 82 relevant reports of drug error (4.1% of all incident report forms). Age of the patients varied from one day to 83 years with a gender ratio of male:female equaled to 33 cases (40.2%):49 cases (59.8%). Eight incidents (9.8%) occurred during anesthesia for pediatric patients under 15 years of age. All patients were evenly distributed errors, ASA categories 1, 2, 3, and 4 as followed 29 cases (35.4%), 33 cases (40.2%), 18 cases (19.5%) and two cases (4.9%) respectively. Common types or sites of surgery of drug error incidents were general surgery (31 incidents; 37.8%), orthopedic surgery (11 incidents; 13.4%), gynecological surgery (8 incidents; 9.8%), obstetric surgery (8 incidents; 9.8%), and cardiac surgery (6 incidents; 7.3%), etc. Sixteen incidents (19.5%) were associated with emergency condition. Seventy-two incidents (87.8%) occurred with general anesthesia while nine incidents (10.9%) occurred with spinal anesthesia with a single report (1.2%) pertaining to brachial plexus block.

Location of incidents and phase when drug error incidents were alerted are shown in **Table 1**. Nurse anesthetists prepared drug and administered the medication in 52 incidents (63.4%) and 32 incidents (39.0%) respectively, while anesthesiologists and nurse anesthetists were the people who detected the error in 40 incidents (48.8%) and 37 incidents (45.1%) respectively. Details of the people who prepared and administered the drug, and detected the error are also demonstrated in **Table 1**. The people who prepared and administered the drug were same and different persons in 31 incidents (37.8%) and 34 incidents (41.5%) respectively. The people who administered drug and detected the incidents were same and different persons in 34 incidents (41.5%) and 31 incidents (37.8%) respectively.

Drugs involved in these incidents are listed in **Table 2**. The commonest incidents were related to nondepolarizing muscle relaxant (23.1%), followed by opioids (21.9%), antibiotics (17.1%), and succinyl choline (7.3%). Among nondepolarizing muscle relaxant, the highest number involved atracurium (8 incidents; 9.7%) and fentanyl (7 incidents; 8.5%) was the most common opioids involved. Types of drug

Table 1. Locations, time when incident alerted, and personals involved with drug error (n = 82)

| | Number | Percentage |
|---------------------------------|--------|------------|
| Location | | |
| Operating room | 75 | 91.5 |
| Recovery room | 7 | 8.5 |
| Time when incidents alerted | | |
| Preinduction | 4 | 4.9 |
| Induction | 19 | 23.2 |
| Maintenance | 47 | 57.3 |
| Emergence | 1 | 1.2 |
| Recovery | 11 | 13.4 |
| Personnel who prepared drug | | |
| Anesthesiologists | 14 | 17.1 |
| Nurse anesthetists | 52 | 63.4 |
| Residents | 14 | 17.1 |
| Students | 4 | 4.9 |
| Personnel who administered drug | | |
| Anesthesiologists | 26 | 31.7 |
| Nurse anesthetists | 32 | 39.0 |
| Residents | 7 | 3.7 |
| Students | 1 | 1.2 |
| Personnel who detect error | | |
| Anesthesiologists | 40 | 48.8 |
| Nurse anesthetists | 37 | 45.1 |
| Residents | 4 | 4.9 |
| Students | 0 | 0 |

Table 2. Drugs involved in drug error incident

| | Number | Percentage |
|---------------------------------|--------|------------|
| Nondepolarizing muscle relaxant | 19 | 23.1 |
| Opioids | 18 | 21.9 |
| Antibiotics | 14 | 17.1 |
| Succinyl choline | 6 | 7.3 |
| Induction agents | 5 | 6.1 |
| Sedatives | 4 | 4.9 |
| Miscellaneous | | |
| prostigmine + atropine | 2 | 2.4 |
| ondansetron | 2 | 2.4 |
| ephedrine | 2 | 2.4 |
| dopamine | 2 | 2.4 |
| 70% alcohol | 1 | 1.2 |
| heparin | 1 | 1.2 |
| diltiazem | 1 | 1.2 |
| syntocinon | 1 | 1.2 |
| insulin | 1 | 1.2 |
| atropine | 1 | 1.2 |

error are demonstrated in **Table 3**. Some incidents related to more than one type of error such as wrong concentration incident occurred together with underdosage or overdosage of drug.

Types of drug related incidents including near miss or pre-error incidents are shown in **Table 3**. Wrong drug administration (29 incidents, 35.3%) and overdosage of drug (27 incidents, 32.9%) were the most frequent types of error. Fourteen incidents (17.1%) of syringe swap and six incidents (7.3%) of ampule swap were revealed as mechanism of drug error. Four incidents (4.9%) involved administration of drug with contraindication or without indication. Of the 25 incidents of drug substitutions, 15 incidents (60%) involved the administration of a drug belonging to a different pharmacological class from the one intended such as muscle relaxant instead of opioids. Two incidents (2.4%) of intra-class drug errors occurred while wrong antibiotic was sent from ward to operating room.

Among patients with overdosage of drugs, six incidents (7.3%) and five incidents (6.1%) related to pediatric patients was haste, and problem with labeling respectively.

Among 15 near-miss incidents (18.3% of all incidents) of drug error, there were seven incidents (8.5%) of wrong drug administration, four incidents (4.9%) of problem with labeling, three incidents (3.6%) of wrong concentration, and one incident (1.2%) of contamination. In the near-miss or pre-error incidents, there were five (6.1%) incidents that error was detected by the same person who prepared drug whereas 10 incidents (12.2%) were detected by different persons.

Sixty-two incidents (75.6%) of drug error occurred without negative outcome of patients. Eight

patients (9.8%), and nine patients (10.9%) developed minor physiologic responses and major respiratory changes resulting in intubation or prolonged-intubation. Other incidents contributed to unplanned intensive care unit admission, local anesthetic toxicity, or severe postoperative pain (1 incident each).

After review by three senior anesthesiologists, 41 incidents (50%), 25 incidents (30.5%), 30 incidents (36.6%), and 32 incidents (39%) were considered to be rule-based, knowledge-based, skill-based, and system errors, respectively. Sixty-five incidents (69.2%) were considered as preventable. The contributing factors, factors minimizing incidents, and suggested corrective strategies for preventing of drug errors are shown in **Table 4**.

Discussion

Adaptation of the critical-incident technique was used to collect incident reports of anesthesia-related adverse events including drug error. The 4.1% incidence of cases involving drug error report to the Thai AIMS database was comparable to the 7% of the Australian Incident Monitoring study of 2000 reports [8]. Drug related incidents have been reported in several studies with the incidence up to 32% of incident reports [11-13]. In 2001, Webster et al revealed an incidence of one drug administration error for every 133 anesthetics, with one in every 200 involving intravenous bolus injection in a prospective registry study [14]. In our study, reporting was anonymous and voluntary, which was numerable to variation in the degree of compliance. Moreover, pre-errors or near-miss were reported only in one-fifth of errors. This might be due to less awareness of certain types of pre-error than of errors. Therefore, many pre-errors might not be reported.

Table 3. Types of drug error incident (n = 82)

| | Pre-error (near miss) | Error | Total | |
|-----------------------|--------------------------|-------|--------|------------|
| | | | Number | Percentage |
| wrong person | 0 | 1 | 1 | 1.2 |
| wrong drug | 7 | 23 | 29 | 35.4 |
| wrong route | 0 | 0 | 0 | 0 |
| problem with labeling | 4 | 8 | 12 | 14.6 |
| wrong concentration | 3 | 5 | 8 | 9.8 |
| overdosage of drug | 0 | 27 | 27 | 32.9 |
| underdosage of drug | 0 | 4 | 4 | 4.9 |
| omit dose | 0 | 7 | 7 | 8.5 |
| omit record | 0 | 2 | 2 | 2.4 |
| drug contamination | 1 | 0 | 1 | 1.2 |

Data are not mutually exclusive

Table 4. Contributing factors, factors minimizing incidents and suggested corrective strategies for drug error

| | Number | Percentage |
|--|--------|------------|
| Contributing factors | | |
| Haste | 35 | 42.7 |
| Lack of experience | 18 | 22.0 |
| Miscommunication | 13 | 15.9 |
| Problem with labeling | 12 | 14.6 |
| Lack of knowledge | 9 | 11.0 |
| Misjudgment | 7 | 8.5 |
| Fatigue | 6 | 7.3 |
| Inadequate personnel | 3 | 3.7 |
| Emergency condition | 3 | 3.7 |
| Other | 2 | 2.4 |
| Factor minimizing incidents | | |
| Vigilance | 59 | 72.0 |
| Experience | 25 | 30.5 |
| Communication | 17 | 20.7 |
| Practice guidelines | 9 | 11.0 |
| Experienced assistant | 3 | 3.7 |
| Adequate staff | 3 | 3.7 |
| Supervision | 2 | 2.4 |
| Equipment maintenance | 1 | 1.2 |
| Suggested corrective strategies | | |
| Practice guidelines | 44 | 53.7 |
| Quality assurance | 33 | 40.2 |
| Improvement of communication | 20 | 24.4 |
| Training | 16 | 19.5 |
| Improvement of supervision | 11 | 13.4 |
| Increasing manpower | 4 | 4.9 |
| More equipment | 1 | 1.2 |

One-fifth of reported incidents were associated with emergency procedures while common types or sites of surgery related to drug error in our study associated to general, orthopedic, obstetric, gynecological, and cardiac surgery. Anesthesia for pediatric patients and cardiac surgery required highly complex task of administering an intravenous drug. Fraind et al revealed that each drug administration can be associated with up to 40 component steps in task analysis of intravenous drug and fluid administration processes in the operating theater [15]. Therefore, it is not surprising that drug pre-errors or errors can easily occur. In a survey of anesthesiologists in New Zealand, 89% respondents admitted to having made a drug error event at some stage during their anesthetic practice and 12.5% admitted to having harmed their patients [16]. A recent survey of quality and safety in anesthesia service in

Thailand found that 8% and 24% of respondents also admitted to having experience of medication error and error related to infusion pump [17].

Most incidents of drug errors occurred in operating room, while only 8.5% were detected in the post-anesthesia care unit. Common phases of anesthetic management when incidents were alerted in present study were maintenance (57.3%) followed by induction (23.2%) and recovery (13.4%). These were different to previous study that drug error occurred more frequently during induction phase [18, 19]. Nurse anesthetists were the most common person who involved in preparation (63.4%) and administration (39%) of drug in the reported incidents while anesthesiologists were the most common personnel who detected the errors (48.8%). The explanation was nurse anesthetists play a major role in providing anesthesia under supervision of

anesthesiologists particularly in Thai government hospitals. People who prepared and administered the drug related to incidents were same and different person in 37.8% and 41.5% of incidents. These proportions were comparable with our previous study [19]. However, people who administered and detected the drug incidents were same and different person in 41.5% and 37.8% of incidents, which was in contrast with our previous report [19]. The possible explanation is the present study included pre-errors that incident were detected before administration resulting in lower proportion of detector of incidents.

The highest percentage of incidents reported were related to the neuromuscular blocking drug (both depolarizing and non-depolarizing muscle relaxant) followed by opioids and antibiotics. The spectrum of drugs commonly involved in the errors reflects the frequent occurrence of errors during maintenance phase. Administration of neuromuscular blocking agents instead of other drugs might result in a loss of the airway, pulmonary aspiration, as well as occurrence of awareness. Giving thiopental instead of others could result in sudden loss of consciousness or apnea necessitating tracheal intubation. Our data demonstrate that the majority (60%) of substitution errors of drug are of the inter-class variety of drug in the same size syringe, which is similar to previous studies [8, 14, 20]. Giving a different pharmacological class from the drug intended is probably more dangerous than giving a same class drug [21].

Although data in a Norwegian hospital showed a tendency towards reduced total incidence of drug errors but with no statistical significant difference ($p = 0.07$) after implementation of colored syringe label [18]. However, our data suggested that implementation of colored coding during anesthesia practice in Thailand might be advantageous.

Overdosage of drugs was the second most common incident reported to our study. Several reasons were cited, pediatric patients requiring thorough calculation of drug dosage and concentration, haste, problem with labeling, problem with infusion pump. The present study is in accordant with the claims related to drug errors from the ASA Closed Claims Project that the most common types of drug errors were substitution and incorrect dose [22].

Three-quarters of patients related to the drug errors incidents developed no negative outcome. No death, awareness, or permanent injury to a patient

was attributed to a drug error in the present study. Four patients required intubation, five patients required unplanned mechanical ventilation, and one another patient was admitted to the intensive care unit. All patients with negative outcomes had full recovery.

Most of incidents were related to human error and 79.2% were considered as preventable. Human error was defined as situations where established practice was not followed. In the present study, half of incidents were considered as rule-base mistake. Haste (42.7%), lack of experience (22%) and miscommunication (15.9%) were the common contributing factors to drug error incidents. Vigilance (72%) a state of clinical awareness which risky conditions are anticipated or diagnosed and treated promptly, were considered as the most common factor minimizing drug incidents. Therefore, the present study showed that, practice guidelines, quality assurance activity such as morbidity conference, improvement of communication and regular training particularly for the constant change-over of trainee were suggested corrective strategies. About two-fifths of incidents were considered as a systemic or latent errors. In anesthesia department in Thailand, the labels were not color-coded and simple piece of sticky tap was used. In 2009, the RCAT enclosed the clinical guidance of using color-coding for anesthetic drug for prevention of inter-class drug errors.

There were several limitations in our study. It is possible that our study had underestimated the true numbers of incidents reported. In addition, we were unable to estimate the true incidence of drug errors because there was no numerator by nature of incident report study. The lack of blinding of our reviewers may have biased the determination of causality. Regardless of these limitations, after the study reported its findings to the RCAT, in 2009, color coded labels of different drug classes became mandatory according to the Thai Clinical Practice Guidelines for the Prevention of Drug Error.

In summary, drug errors in anesthesia may lead to serious outcomes. Common drug involved were neuromuscular blocking agents, opioids and antibiotics. Giving the wrong drug and overdosage of drug were most common types of error. Majority of incidents were preventable. Suggested corrective strategies were practice guidelines particularly using of class specific color-labeling, quality assurance activity, improvement of communication and training.

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