

Perioperative Anesthetic Adverse Events in Thailand (PAAAd Thai): Incident Reporting Study: An Analysis of 69 Perioperative Adverse Events in Patients Undergoing Cesarean Section

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Background: The Royal College of Anesthesiologists of Thailand initiated registry and reporting of anesthesia service incidents and outcomes in 2015 [Perioperative Anesthetic Adverse Events in Thailand (PAAAd Thai)]. Cesarean section (C-section) was associated with significantly increased risks of anesthesia-related adverse events. All details in these adverse events were important issues to improve maternal safety and outcomes.

Objective: To describe the incidents regarding, characteristics and outcomes of anesthetic-related adverse events in the C-section patients in PAAAd Thai.

Materials and Methods: This study was a multicenter descriptive study of data prospectively collected from 22 hospitals across Thailand between January 1 and December 31, 2015. We extracted relevant data from the incident reports on C-section patients. Three peer reviewers reviewed the completed incident record forms regarding possible mechanisms, contributing factors, appropriate management, and preventive strategies to achieve agreement by a consensus. The data were analyzed by descriptive statistics.

Results: Total 2,206 incidents of adverse events were reported from 333,219 cases in primary PAAAd Thai. The incidents occurred in 57 parturient patients undergoing cesarean section (C-section). Most of C-section patients were ASA physical status class II (54.5%) and mostly were indicated with emergency reasons (57.1%). The most common anesthetic techniques were general anesthesia (59.6%). The common place and period that the events occurs were intraoperative period (63.16%) (including induction, intubation, maintenance and emergence period) and 28.07% of events were preventable. The three common adverse events included desaturation (17.39%), esophageal intubation (15.94 %) and drug error (14.49 %). Most common immediate and long term outcome were major transient physiologic changes and complete recovery (38.78% and 95.56%, respectively). The most common contributing factor was human factor (75.76%) including inexperience, haste, inadequate knowledge (36.36%, 18.18% and 10.61%, respectively). Improved supervision, quality assurance activity, following guideline practice and additional training could be suggestive corrective strategies to minimizing these adverse events.

Conclusion: The authors found that inexperience, haste, and inadequate knowledge were the major contributory factors. Some of them (28%) were preventable and correctable. Supervision, quality assurance, complies to practice guideline and additional training can improve and prevent these serious adverse events, also provide patient safety in the Thai health care system.

Keywords: anesthesia, adverse events, incident report, cesarean section

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Maternal mortality is a major health problem especially in less developed and developing countries. Globally, the maternal mortality ratio (MMR; maternal deaths per 100,000 live births) fell by nearly 44% over the past 25 years, to an estimated 216 maternal deaths per 100,000 live births in 2015, from an MMR of 385 in 1990^(1,2). The two regions with highest MMR in 2015 are sub-Saharan Africa and Oceania^(1,2). The highest decline between 1990 and 2015 was observed in Eastern Asia (72%), followed by Southern Asia (67%), South-eastern Asia (66%) and Northern Africa (59%). In the developing regions, the MMR was 430. The decline in developed regions was 48%.

In the developing regions, the overall annual rate of MMR reduction was estimated 2.4% average yearly reduction over the past 25 years. Eastern Asia experienced the highest estimated annual rate of decline with an average yearly MMR decrease of 5.0%. The lowest estimated annual rate of decline occurred in Western Asia, where MMR decreased by 2.2% per year during the same period.

The MMR in Thailand was reported as 37.2 per 100,000 live births in 1987, but by 1998, it had declined to 7.0 per 100,000. However, the MMR increased to 12.3 in 1999 and continued to increase to 13.3 in 2004. In 2015, the MMR in Thailand was 20 (14-32)⁽¹⁾.

In the United States, the Centers for Disease Control and Prevention [CDC] reported that the pregnancy-related mortality ratios were 17.8, 15.9, and 17.3 deaths per 100,000 live births in 2011, 2012 and 2013, respectively⁽¹⁾. The overall pregnancy-related mortality was increased. The causes of pregnancy-related deaths in the United States during 2011–2013 were cardiovascular diseases (15.5%), non-cardiovascular diseases (14.5%) and infection or sepsis (12.7%). But, the cause of death is unknown for 6.1%⁽³⁾.

Anesthesia is emerging as an additional risk factor of concern in studies of maternal deaths. Safety in anesthesia is the important issues in cesarean section patients. Good monitoring and analysis of the critical adverse events to find risk factors that lead to corrective strategies is the effective tools to improve patient safety in anesthesia care. In Thailand, the Thai Anesthesia Incidents study (THAI study) in 2005⁽⁴⁾ reported qualitative data of adverse event related to anesthesia across Thailand. The critical incident analysis was followed by THAI-AIMS study in 2007 that includes anesthesia-related complications of caesarean delivery⁽⁵⁾. The incidence of anesthetic complication in parturients was 35.9:10,000. Incidence of death related anesthesia was 4.8%⁽⁵⁾. Causes of maternal

mortality include hemorrhage (37%), embolism (11.7%), hypertension (10%), infection (8.5%), and anesthesia (3.1%)⁽⁶⁾.

After THAI-AIMS study, there were several consequent changes to anesthesia practice guidelines. In 2015, RCAT hosted the PAAAd Thai study⁽⁷⁾ to investigate the incidents of anesthesia adverse events, contributing factors and to suggest strategies to avoid critical adverse events. This study was focusing on adverse events that occurred in obstetric patients who undergoing cesarean section (C-section), to determine the characteristics of patients, incident mechanism, outcomes, factors contributing to the incidents and corrective strategies.

Materials and Methods

Design and setting

Perioperative Anesthetic Adverse Events in Thailand [PAAAd Thai] was a multicenter prospective observational study including 22 hospitals across Thailand⁽⁸⁾. The hospitals were chosen among hospitals previously involved in the Thai Anesthesia Incident Monitoring Study (Thai AIMS), based on their agreement to participate in reporting the adverse events anonymously. Data were collected between January 1 and December 31, 2015.

Ethic Committee [EC] or Institutional Review Board [IRB] in each site approved the study protocol before the study collecting the data. Informed consent was exempted due to the observational nature of the study.

All specific anesthesia-related adverse events during the study period were eligible for inclusion.

This article focuses on the incidents of adverse events reported in C-section patients regarding, characteristics and outcomes, incident mechanism, contributory factors and corrective strategies.

Data collection and statistical analysis

An incident record form was collected and completed by anesthesiologists or nurse anesthetists. The data was validated by an expert committee, which included experienced anesthesiologists from the participating hospitals and sent to the data management center. After checking and organizing the data by the data management manager, the data form was put into the central computerized database.

In this study, we extracted the data of adverse events in C-section patients and reported all of important data including the demographic data, place and period of occurrence, anesthetic management,

intra-operative events and peri-operative complications among consecutive patients within 24 hours of the postoperative period, level of anesthetic attribute to event, and preventability. Each case was reviewed by the preliminary quality assurance [QA] committee, subsequently we distributed these data to at least 3 peer reviewers to independently identify the incident mechanism, contributory factors, appropriated management and corrective strategies. Any disagreement was critically discussed and judged to achieve a consensus. The workshop and internal audit were performed during an extensive introductory phase to ascertain the standardization.

The descriptive statistics were used to summarize the data by using SPSS for Windows, version 22 (IBM Corp, Armonk, NY, USA).

Results

In the database of 2,206 incidents reported from 2,000 patients in PAAad Thai study, 74 incidents of parturient undergoing cesarean section was reported⁽⁸⁾. After we extracted all of the data form, the peer reviewer reviewed and agreed that the truly adverse events occurred in only 57 patients with 69 incidents. Patient characteristics are summarized in Table 1. Most of C-section patients were categorized in ASA physical status class II (73.68%) and mostly were indicated with emergency reasons (57.89%). The most common anesthetic techniques were general anesthesia (61.40%).

Three out of 57 cases of C-section patients developed cardiac arrest. One occurred in the university hospital and two in the non-university tertiary hospital (2 cases). Mortality rate was 2.9% [2 cases: university (1 cases) and tertiary hospital (1 cases)] (Table 1).

Table 2 show place and period of occurrence, of which the majority of adverse events occurred in the intraoperative period (63.1%). Adverse outcomes were documented to be preventable in 28.07% of patients and partially preventable/unpreventable in 71.93%.

The occurrence of adverse events was 69 incidents. (One patient can have more than one incident). The three most common adverse events in C-section patients were desaturation (17.39%), esophageal intubation (15.94 %) and drug errors (14.49 %) (Table 3). Death related anesthesia (2 cases) occurred only in postoperative period within 24 h. No adverse event occurred in ICU.

There was no incidents of unplanned ICU admission, pulmonary aspiration, failed intubation, coma / CVA / convulsion from the present study.

Table 1. Demographic data of all c-section patients with incident report (n = 57)

Characteristics	All c-section n (%)
ASA Physical status	
2	42 (73.68)
3	15 (26.32)
Emergency cases	33 (57.89)
Non-office hour	15 (26.32)
Age: mean (SD)	32.05(10.27)
Weight: mean (SD)	72.02 (15.71)
Height: mean (SD)	157.98 (6.49)
Anesthetic duration(min): mean (SD)	65.12 (31.40)
Anesthetic technique:	
General anesthesia(GA)	35 (61.40)
Spinal anesthesia (SB)	21 (36.84)
Epidural anesthesia (EDB)	1 (1.8)
Sites	
University hospitals	13 (22.8)
Tertiary (regional) hospitals	44 (77.2)
Cardiac arrest (%)	3 (5.26)
University hospitals	1 (33.33)
Tertiary (regional) hospitals	2 (66.67)
Death (%)	2 (3.51)
University hospitals	1 (50.00)
Tertiary (regional) hospitals	1 (50.00)

Table 2. Place and period of occurrence and preventability (n = 57)

Variables	n (%)
Place and period of adverse event	
Intraoperative	36 (63.16)
Postanesthetic care unit (PACU)	14 (24.56)
Ward 24-hr postoperative	7 (12.28)
Preventability	
Preventable	16 (28.07)
Partial preventable/ Unpreventable	41(71.93)

Within 24 hours following adverse outcomes, thirty parturients (61.23%) had transient physiologic changes (minor and major), cardiac arrest (6.13%), and death (4.08%). Twenty-four hours but within 7 days after the events, 41 (95.56%) parturient had complete recovery, and there were three cases of prolonged respiratory support (4.44%) (Table 4).

For system analysis (Table 7), the most important

Table 3. Order of frequency of anesthetic-related adverse events in caesarean section parturient stratified by perioperative periods within 24 h

Adverse events	Total events		Period					
			Intraoperative		PACU		PO 24-hr	
	n	%	n	%	n	%	n	%
Desaturation	12	17.39	5	7.25	6	8.70	1	1.45
Esophageal intubation	11	15.94	11	15.94	0	0.00	0	0.00
Drug error	10	14.49	10	14.49	0	0.00	0	0.00
Re-intubation	8	11.59	1	1.45	6	8.70	1	1.45
Anaphylaxis	6	8.70	4	5.80	2	2.90	0	0.00
Nerve injuries	4	5.80	0	0.00	0	0.00	4	5.80
Cardiac arrest	3	4.35	2	2.90	0	0.00	1	1.45
Difficult intubation	3	4.35	3	4.35	0	0.00	0	0.00
Death related to anesthesia	2	2.90	0	0.00	0	0.00	2	2.90
Total spinal block	2	2.90	2	2.90	0	0.00	0	0.00
Endobronchial intubation	2	2.90	2	2.90	0	0.00	0	0.00
Equipment Malfunction / Failure	2	2.90	2	2.90	0	0.00	0	0.00
Pulmonary embolism	1	1.45	1	1.45	0	0.00	0	0.00
Awareness	1	1.45	0	0.00	0	0.00	1	1.45
Suspected MI/Ischemia	1	1.45	1	1.45	0	0.00	0	0.00
Severe Arrhythmia	1	1.45	1	1.45	0	0.00	0	0.00
Total (57 case)	69	100.00	45	65.22	14	20.29	10	14.49

PACU = Postanesthetic care unit, PO 24-hr = postoperative 24 hours

contributing factors included inexperience (36.36%), haste (18.18%), inadequate knowledge (10.61%) and inadequate preoperative evaluation (10.61%). Inexperience was the most contributing factor found in tertiary hospitals (66.67%) more than university hospitals (33.33%).

Factors for minimizing incident included more experience, high vigilance and experienced assistant

(34.07%, 30.77% and 25.27%, respectively).

The majority of reports suggested corrective strategies including improved supervision (27.03%), quality assurance activity (25.68%), additional training (20.27%), and follow guideline practice (20.27%) (Table 7). Improved supervision was the most suggesting corrective strategies found in tertiary hospital more than university hospital (88.89% vs. 76.92%).

Table 5 shows the distribution of anesthesia provider in university hospitals and tertiary hospitals. Mostly anesthesia providers who took care the C-section patients in university hospital were anesthesia residents; while in tertiary hospital were nurse anesthetists. The number of adverse events were highest occurred with anesthetic providers who worked for 1-3 years and work more than 5 years (Table 6).

Table 4. Outcome of management (n = 47)

Outcome	n	%
Immediate outcome (within 24 hour)*		
Complete recovery	14	28.57
Minor transient physiologic change	11	22.45
Major transient physiologic change	19	38.78
Cardiac arrest	3	6.12
Death	2	4.08
Long term outcome (> 24 hours to 7 days post-operative)*		
Complete recovery	41	95.56
Prolonged respiratory support	3	4.44
Vegetative / brain death	0	0.00
Death	0	0.00

*missing data = 10 cases

Discussion

In this study, we focused on 57 C-section parturient patients who developed at least one of undesirable anesthesia-related adverse events. Despite a policy established by the Royal College of Anesthesiologists of Thailand (RCAT) to improve the outcome, the reported incidents of such undesirable events still

Table 5. Adverse events related with anesthesia provider in university hospital and tertiary hospital (n = 57)

Anesthesia providers		University hospital		Tertiary hospital		Total	
		n	%	n	%	n	%
1	Anesthesiologists	3	23.08	8	18.18	11	19.30
2	Nurse anesthetists	1	7.69	19	43.18	20	35.09
3	Anesthesia residents	5	38.46	2	4.55	7	12.28
4	Anesthesiologists + Nurse anesthetists	1	7.69	9	20.45	10	17.54
5	Anesthesiologists + Anesthesia residents	1	7.69	0	0	1	1.75
6	Anesthesiologists + Anesthesia residents + Nurse anesthetists	2	15.38	0	0	2	3.51
7	Surgeons	0	0	1	2.27	1	1.75
8	Medical students	0	0	2	4.55	2	3.51
9	Nurse anesthetist trainees	0	0	3	6.82	3	5.26
Total		13	100.00	44	100.00	57	100.00

persisted in our study. Globally, the estimated incidence of adverse events in C-section parturients varied between 0.73 and 13.8%^(3,5,13,14). C-section was demonstrated to be a risk factor of anesthesia-related complications (odds ratio [OR] 2.51, 95% confidence interval [CI] 2.36–2.68)⁽¹⁴⁾. Hence, giving anesthesia to C-section is a big challenge particularly in lower or middle income countries (LMIC) where the maternal mortality ratio (maternal deaths per 100 000 live births) is 14 times higher than that in high-income countries (HIC)⁽¹²⁾.

The multivariate logistic regression revealed. In our study, mostly of the adverse events occurred in intraoperative period (63.16%) during emergency C-section (57.89%) where the pre-anesthesia care for maternal patients was often limited due to the emergent nature of the obstetric events. This could be part of reasons why the incidence in the present study was higher than that in some previous studies.

General anesthesia was the dominant method (61.40%) in our setting which differed from the common practice in other previous studies^(3,5,13,14) where regional anesthesia were prominent. This is due to the incidents occurred mostly in non-university tertiary care hospitals (77.2%) where only general anesthesia was allowed to be practiced by nurse anesthetists. The 2007 American Society of Anesthesiologists Practice Guidelines for Obstetric Anesthesia stating “neuraxial techniques are preferred to (general anesthesia) for most cesarean deliveries” contrasted with the 1999 statement that “the decision to use a particular anesthetic technique should be individualized”^(15,16).

In German⁽¹³⁾, the incidence of anesthetic-related complications remains low. This is due primarily to the increasing use of regional anesthesia as general anesthesia is associated with a 17-fold increase

Table 6. Anesthesia provider experience correlated with number of adverse events occurs (n = 33)

Anesthesia provider experience (year)	Number of events	%
≤1	3	9.09
>1-3	13	39.39
>3-5	4	12.12
>5	13	39.39

*missing data 24 cases

in complications, in particular failed endotracheal intubation, aspiration of gastric contents and hypoxia. It is most important that all obstetric patients deemed at risk for general anesthesia.

Sobhy et al⁽¹⁰⁾ have compiled the first systematic review and meta-analysis of anesthesia related maternal mortality in low-income and middle-income countries. Total 44 studies (632,556 pregnancies) reported risks of death from anesthesia in women who had an obstetric surgical procedure. The risk of death from anesthesia in women undergoing obstetric procedures was 1.2 per 1000 women. Exposure to general anesthesia increased the odds of maternal and perinatal deaths (odds ratio 3.3 and 2.3, respectively) compared with neuraxial anesthesia. The overall frequency of anesthesia-related maternal death is 300-fold higher for neuraxial anesthesia and 900-fold higher for general anesthesia than that reported from the USA⁽¹⁷⁾ (1.2 per 1000 women undergoing an obstetric procedure vs. 3.8 per million, and 5.9 per 1000 vs. 6.5 per million, respectively). In our study, we found that the causes of death were postpartum hemorrhage and ST elevated myocardial infarction.

The three most common anesthesia-related

Table 7. Contributing factors, factors minimizing incident and suggestive corrective strategies (n = 57)

Variables	n = 57	%
Contributing factors		
Human factors		
Inexperience	24	36.36
Haste	12	18.18
Inadequate knowledge	7	10.61
Inadequate decision	6	9.09
Error in drug label	1	1.52
Facility failure		
Inadequate preoperative evaluation	7	10.61
Communication failure	2	3.03
Equipment: inadequate/ineffective	1	1.52
Patient condition		
Emergency condition	4	6.06
Other	2	3.03
Factors minimizing incident		
Having experience	31	34.07
High vigilance	28	30.77
Experienced assistant	23	25.27
Good communication system	4	4.40
Good consultation system both in and between departments	2	2.20
Equipment maintenance and check up	2	2.20
Comply to guidelines	1	1.10
Suggestive corrective strategies		
Improved supervision	20	27.03
Quality assurance activity (M&M)	19	25.68
Guideline practice	15	20.27
Additional training	15	20.27
Improved communication	4	5.41
More manpower	1	1.35

adverse events in the present study were desaturation (17.39%), esophageal intubation (15.94 %) and drug error (14.49 %). Compared with THAI-AIMS study⁽⁵⁾, most common adverse events in cesarean delivery were desaturation (13.8%), cardiac arrest (10.2%) and awareness (6.6%). Both studies revealed the most common adverse event was desaturation due to intubation under general anesthesia. The adverse events from regional anesthesia, such as nerve injury (5.80%) and total spinal block (2.90%), were small. The finding was also differed from that in the previous studies^(3,5,13,14) where adverse events related to regional anesthesia were commonly reported. In Guglielminotti J, et al⁽³⁾, adverse events related to neuraxial and

headache with epidural blood patch were highest occurrence in C-section parturients (54.2% and 51.9%). Certainly general anesthesia presents substantial risk. Half of maternal deaths in the current study were attributed to complications of airway management during general anesthesia. Maternal airway management is so difficult; the physiological changes of pregnancy can lead to airway edema, difficult positioning, and decreased oxygen reserves. Although endotracheal intubation is preferred for general anesthesia, when attempts fail, a supraglottic airway device can help to provide ventilation and oxygenation. However, the gastric aspiration may occur with this device⁽¹⁸⁾.

The author distributed these data to at least 3 peer reviewers to independently identify the incident mechanism, contributory factors, appropriated management and corrective strategies. Any disagreement was critically discussed and judged to achieve a consensus. The most contributing factors were inexperience (36.36%), haste (18.18%), inadequate knowledge (10.61%) and inadequate preoperative evaluation (10.61%) (Table 7). These results were different from previous study⁽⁵⁾.

The majority of reports suggested corrective strategies that included improve supervision (27.03%), quality assurance activity (25.68%) additional training (20.27%) and follow guideline practice (20.27%) (Table 7). Improve supervision was the most suggesting corrective strategies that found in tertiary hospital more than university hospital (88.89% vs. 76.92%).

At present, there are many hospitals in Thailand where anesthesia is performed by nurse anesthetists due to the small number of anesthesiologists for the overall Thai population. A nurse anesthetist receives a certificate of training after completion of the program and works under the supervision of either an anesthesiologist or a surgeon.

Data from this study revealed that general anesthesia was mainly administered by nurse anesthetists (35.09%). In university hospitals, attending anesthesiologists supervise the residents and trainees, but in most district hospitals, the surgeons supervise nurse anesthetists giving general anesthesia. In Thailand, the Royal College of Anesthesiologists of Thailand does not allow nurse anesthetists to perform spinal anesthesia.

In low-income and middle-income countries⁽¹⁰⁾, the rate of any maternal death was 9.8 per 1,000 anesthetics when managed by non-physician anesthetists compared with 5.2 per 1,000 when managed by physician anesthetists. There are very few anesthesiologists

and nurse anesthetists compared to the increased population. That is the one important global issue to improve maternal health care. The other reason in rural area may be due to deficits in health infrastructure, medical technology and integration of resources to provide surgery have been consistently correlated with mortality.

The number of adverse event was highest occurred with anesthetic providers who work for 1-3 years and work more than 5 years (Table 6). Anesthetic providers with low experience year were correlated with less adverse events than those with higher experience years. This could be due to negligence and over confidence in high experience year providers.

Limitation

The incident reports were on a resource basis, some incidents might be under-estimated due to no reported. Statistic data from this study cannot compare with Thai AIMs because of difference in the study design. However, we organized several meetings before the participating hospitals agreed to participate in this multicenter project in an attempt to minimize this problem. This study did not include some information such as preoperative condition or underlying that helped to explain precipitating factors.

Conclusion

The authors found that inexperience, haste, and inadequate knowledge were the major contributory factors. Some of them (28%) were preventable and correctable. Supervision, quality assurance, complies to practice guideline and additional training can improve and prevent these serious adverse events, also provide patient safety in the Thai health care system.

What is already know on this topic?

Improve trend in anesthesia and perioperative care from tertiary hospital both university and regional hospital that could reduce severity of mortality rate when compared with Thai study.

What this study adds?

This article found that inexperience, haste, and inadequate knowledge were the major contributory factors. Some of them (28%) were preventable and correctable.

Supervision, quality assurance, complies to practice guideline and additional training can improve and prevent these serious adverse events, also provide patient safety in the Thai health care system.

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Potential conflicts of interest

The authors declare no conflict of interest.

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