Original Article

Anesthetic related Adverse Events by Incidence Report in HRH Princess Maha Chakri Sirindhorn Medical Center

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Objective: The objective of the present study was to evaluate the incidence of all complications and contributing factors after receiving anesthesia within HRH Princess Maha Chakri Sirindhorn Medical Center.

Materials and Methods: This prospective descriptive study included 2,285 patients who received anesthesia services from the Department of Anesthesiology. Data was collected from August 2019 to January 2020 and analyzed with STATA software version 15.

Results: In 2,285 patients who received anesthesia services, there were a total of 1,180 complications, which represented in an incidence rate of 51.64%. More than half of these complication were preventable. 93.42% were minor adverse events. The majority of the population was adult age over 18 years old, with average age of 47.8 years old. Most were female (59.17%), ASA class 2 (43.19%) and received general anesthesia technique (48.89%). The most common anesthetic complications were hypotension, sore throat, nausea/vomiting and shivering respectively. The most common major anesthetic complication was cardiac arrhythmia.

Conclusion: The incidence rate of anesthetic complication was 51.64%. The most common complications were hypotension, nausea/vomiting and shivering. Factors that contributed to anesthetic complications were female gender, age >65, pregnancy, long operative time, and positions other than supine. Factors that minimized the risk were minor operation, TIVA and other anesthesia techniques and supervision.

Keywords: Anesthesiology; Safety; Complications; Postoperative; Perioperative; Operation; Patient

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Anesthesia involves many kinds of risks to patients in every process. These risks include minor and major events that increase both morbidity and mortality, and consequently burden the whole hospital system. Many of which are preventable. To reduce the complications, individual hospital needs a strategy to modify these risks and prevent complications.

Previous studies had investigated the perioperative and anesthetic adverse events in Thailand[1, 2]. Nevertheless, the population was large and diverse, so the result could not be applied to all hospitals in Thailand due to differences in many circumstances. Thai public health system is respectable at getting people through the health system easily and swiftly. However, this implies that health care providers are loaded with works and unlimited workhours. The scarcity magnifies when it comes to distribution in the upcountry. The lack of personnel and exhaustion might contribute to more complications.

HRH Princess Maha Chakri Sirindhorn Medical Center is a tertiary-care university hospital, which operates on more than 6,000 surgical patients yearly. The author recognizes that there is no written record keeping track of the anesthetic adverse outcomes in the hospital. While the safety of patients is the priority, we fail to adequately examine situations without proper records. To improve the system and create safety policy for practice on our patients, the author recognizes the importance of data recording of incident report in regard to anesthetic related adverse events in HRH Princess Maha Chakri Sirindhorn Medical Center.

The objective of this study was to evaluate the incidence of all complications and contributing factors after receiving anesthesia within HRH Princess Maha Chakri Sirindhorn Medical Center.

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Materials and Methods

The author used a prospective descriptive/ observational study design, which was approved by the hospital ethics committee, EC approval No. SWUEC/E-024/ 2562 TCTR identification number TCTR20210311006. Patients who received anesthesia services from the department

of anesthesiology, HRH Princess Maha Chakri Sirindhorn Medical Center from August 2019 to January 2020 were recruited. The sample size was calculated to be 2,285 based on the Daniel, 1999 formula and data from the PAAd Thai Study: Perioperative and Anesthetic Adverse events in Thailand[2]. Thus, the present study used 2,285 participants. All 2,285 patients had given written informed consent and was followed-up within 24 postoperative hours. Ambulatory cases were followed-up by phone. A standardized report form, with close and open-end questionnaire, was developed to record general information of each patient, operation, anesthetic data, and day incident case happened. The data were calculated by the STATA software version 15.0. The categorical variables were presented in frequency and percentage. The continuous variables were shown in median (interquartile range [IQR]) due to non-normal distribution. The 95% confidence interval (95% CI) and odds ratio were analyzed based on normal approximation to binomial distribution. The multivariate logistic regression model was used to explore the factors that were associated with complication.

Results

During the 6 months period between August 2019 and January 2020, 1,180 adverse events were reported in 2,285 patients who received anesthesia services. The demographic data revealed that the patient aged ranging from 1 month to 100 years old, with a mean age of 47.8 years, and most of them were female (59.17%). In terms of anesthetic techniques, just under half received general anesthesia, almost a quarter received Total Intravenous Anesthesia (TIVA), and slightly more than one-fifth received spinal anesthesia by 48.89%, 24.82% and 22.89%, respectively. The vast majority of elective and emergency patients fell within the ASA II category. The NPO time was reported to be 15 hours on average (Table 1).

General surgery, obstetrics and gynecology, and orthopedic were the most common procedures, accounting for 36.1%, 24.59%, and 20.65%, respectively. Obstetrics had the highest rate of complications among these procedures (71.08%) (Figure 1).

The incidence rate of anesthetic complication in this study was 51.64%. Almost all of the complications were minor (91.61%) and 65.76% of them could have been avoided. In this study, the figure for cardiovascular adverse events was shown to be 57.03% among the top three most prevalent issues. Hypotension was the most common adverse event; cardiac arrhythmia was one of the problems that led to the biggest problem, according to the complications recorded. In this study, there were three patients with cardiac arrest who were in an emergency situation (ASA 4E).

The majority of adverse events, 91.29%, did not have impact on the patients that lasted more than 24 hours. However, 8% of these cases required prolonged ventilatory support, prolonged hospital stay, necessitating further medical attention. Among these cases, 68% had fully recovered, and 32% required further treatment.

Table 1. Demographic data (n=2,285)

	Number	%
Gender		
Male	933	40.83
Female	1,352	59.17
Age (year)		
Mean (SD)	47.8 (19.04)	
Median (P25, P75)	49 (33, 62)	
Weight (kg.)		
Mean (SD)	63.32 (15.61)	
Median (P25, P75)	62 (54, 72)	
Height (cm.)		
Mean (SD)	159.78 (14.28)	
Median (P25, P75)	160 (155, 167)	
BMI (kg/m^2)		
Mean (SD)	24.7 (5.45)	
Median (P25, P75)	24.08 (21.09, 27.63)	
NPO time (hr.)		
Mean (SD)	15.8 (12.71)	
Median (P25, P75)	15 (11, 18.45)	
Type of anesthetic technique		
GA	1,117	48.89
Spinal	523	22.89
MAC	567	24.81
Others	78	3.41
ASA		
1/1E	166/52	7.26/2.28
2/2E	987/275	43.19/12.04
3/3E	570/147	24.95/6.43
4/4E	24/60	1.05/2.63
5/5E	0/4	0/0.18

SD = Standard deviation; GA = general anesthesia; MAC = monitored anesthesia care

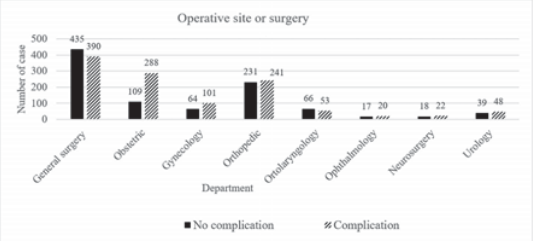

Figure 1. Operative site or surgery.

According to Table 3, the contributing factors for the anesthetic complication were divided into patient factors,

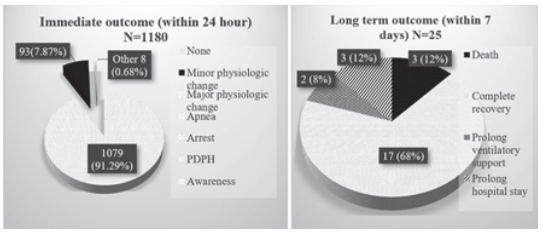

Figure 2. Immediate adverse events outcome and long-term adverse events outcome.

operation factors and anesthetic factors. Patient factors included female gender, age older than 65 and obesity. Operative factors included position, CVT operation and operative duration of longer than 60 minutes. Anesthetic factors included general anesthesia and medical student performer.

Discussion

The incidence rate of anesthetic complication was 51.64% of which 65.76% were preventable such as hypotension, shivering and nausea/vomiting. Furthermore, 93.42% of these preventable events were minor. The open-ended questionnaire suggested that these events were predictable and occurred repeatedly in similar situation. Therefore, if we could manage this, the overall complications would significantly decrease. Minor complications often led to nonfatal outcome, but it was frequently a beginning of the Swiss cheese model that we should not overlook[3]. Minor events could result in considerable negative effects on the patients, as well as the healthcare workers involved[4].

The greater reports for hypotension might be altered by female gender being dominated. Owing to the higher rate of obstetrics service in HRH Princess Maha Chakri Sirindhorn Medical Center, cesarean section rate was 50%. Physiologic change in these pregnant women might be a confounding factor to the database and result. According to Table 3, pregnancy was a contributing factor to complication by 4-fold.

Furthermore, we analyzed data to explore the factors that were associated with complications. According to Table 3, female gender was 1.56-fold more likely to be at risk of complications compared to male. Age under 18 years old was a protective factor by 32% compared to normal adults. While extreme ages beyond 85 increase the risk by 19%, old age (65 to 84) increased more by 33%. An extreme age (>85) population in our study tends to have lower risk than the elderly (65 to 84) because of the awareness of the anesthesia personnels in these vulnerable age groups. Univariate analysis also demonstrated an association between higher BMI a risk for complications with a p-value of 0.139 as computed from multi-variated analysis.

With the technology epoch and introduction of more substate, anesthesia progression had become a saver practice[5,6]. Even so, human errors still occur. With advance equipment, machinery and safety checklist[7-10], the results in developed, compared to developing nations were not different[11]. This might be due to general clinical practice

Table 2. Incidence of complication

Complication (% of total)	n (%)
Complication	1,180 (51.64)
Minor	1,081 (91.61)
Major	99 (8.39)
Preventable	776 (65.76)
Minor	725 (93.42)
Major	51 (6.57)
Cardiologic complication, n=673 (57.03)	
Hypotension	539 (80.09)
Cardiac arrhythmia	46 (6.84)
Hypertension	36 (5.35)
Bradycardia	33 (4.90)
Cardiac arrest	3 (0.45)
Other: hypovolemia volume overload	16 (2.38)
Respiratory complication, n=354 (30.0%)	
Sore throat	253 (71.47%)
Hoarseness	42 (11.86%)
Esophageal intubation	13 (3.67%)
Desaturation	12 (3.39%)
Bronchospasm/Laryngospasm	10 (2.82%)
Unintended extubation	2 (0.56%)
Pulmonary aspiration	1 (0.28%)
Pneumothorax	1 (0.28%)
Atelectasis	1 (0.28%)
Other: cut lip, dental trauma	19 (5.37%)
Neurologic complication, n=149 (12.63)	
Dizziness	133 (89.26)
High block/total block	5 (3.36)
Peripheral nerve damage	1 (0.67)
Delirium	1 (0.67)
Postoperative visual loss	1 (0.67)
Other: backache, headache	8 (5.37%)
GI/GU complication, n=324 (27.46)	
Nausea/vomiting	311 (95.99)
Oliquria/anuria	10 (3.09)
Other	3 (0.93%)
Others, n=287 (24.32)	
Shivering	154 (53.66)
Itching	118 (41.11)
Muscle pain	13 (4.53)
Hypothermia	1 (0.35)
Abrasion wound	1 (0.35)

Table 3. Factor contribute to complication

Variables	Crude OR (95% CI)	Adjusted OR (95% CI)	p-value
Gender			
Male	1.00	1.00	
Female	1.86 (1.57 to 2.20)	1.56 (1.25 to 1.94)	
Age			0.036
1 to 18	0.56 (0.37 to 0.86)	0.68 (0.41 to 1.13)	
18 to 64	1.00	1.00	
65 to 84	0.90 (0.73 to 1.12)	1.33 (1.02 to 1.73)	
≥85	0.76 (0.40 to 1.44)	1.18 (0.57 to 2.41)	
BMI			0.139
<17	0.97 (0.65 to 1.47)	1.02 (0.63 to 1.66)	
17 to 24.99	1.00	1.00	
25 to 29.99	1.48 (1.22 to 1.80)	1.19 (0.95 to 1.49)	
30 to 39.99	1.61 (1.25 to 2.08)	1.10 (0.81 to 1.50)	
≥40	2.12 (0.94 to 4.79)	1.68 (0.58 to 4.83)	
Smoking			0.798
No	1.00	1.00	
Yes	0.77 (0.59 to 0.99)	1.05 (0.72 to 1.53)	
Drinking			0.464
No	1.00	1.00	
Yes	0.84 (0.66 to 1.07)	1.14 (0.81 to 1.60)	
Pregnancy			
No	1.00	1.00	
Yes	5.52 (3.96 to 7.69)	4.62 (2.91 to 7.32)	
NPO (hours)			0.339
≤6	1.00	1.00	
>6 to 12	1.10 (0.76 to 1.60)	1.24 (0.80 to 1.94)	
>12 to 24	1.09 (0.76 to 1.55)	1.24 (0.80 to 1.92)	
>24	0.76 (0.46 to 1.25)	1.18 (0.66 to 2.13)	
Operative site			<0.001
Major	1.00	1.00	
Obstetric	0.57 (0.40 to 0.81)	0.79 (0.49 to 1.27)	
Orthopedic	0.80 (0.65 to 0.99)	0.75 (0.55 to 1.02)	
Minor	0.65 (0.51 to 0.82)	0.55 (0.41 to 0.73)	
Med	0.14 (0.08 to 0.25)	0.44 (0.23 to 0.84)	
CVT	2.10 (0.66 to 6.62)	1.97 (0.51 to 7.68)	
ASA			0.250
ASA1,2	1.00	1.00	
ASA3,4,5	0.90 (0.74 to 1.10)	0.96 (0.74 to 1.25)	
ASA 1E,2E	1.13 (0.89 to 1.45)	0.97 (0.70 to 1.34)	
ASA 3E,4E,5E	1.12 (0.84 to 1.51)	0.80 (0.55 to 1.17)	
Operation time (minutes)			<0.001
≤60	1.00	1.00	
>60 to ≤180	3.04 (2.51 to 3.68)	1.84 (1.41 to 2.40)	
>180	4.53 (3.45 to 5.94)	2.54 (1.78 to 3.63)	

BMI = body mass index; NPO = nothing per oral; CVT = cardiovascular thoracic surgery; ASA = American Society of Anesthesiologists physical status; GA = general anesthesia; TIVA = total venous anesthesia

Table 3. Cont.

Variables	Crude OR (95% CI)	Adjusted OR (95% CI)	p-value
Anesthetic technique			<0.001
GA	1.00	1.00	
Spinal	1.30 (1.05 to 1.62)	0.83 (0.62 to 1.13)	
TIVA	0.19 (0.15 to 0.24)	0.21 (0.14 to 0.31)	
Others	0.10 (0.05 to 0.20)	0.14 (0.07 to 0.27)	
Anesthetic performer			0.037
Staff, Resident and Nurse	1.00	1.00	
Staff and Others	0.59 (0.49 to 0.72)	0.81 (0.65 to 1.01)	
Resident and Others	0.70 (0.55 to 0.90)	0.73 (0.54 to 0.98)	
Others and Medical student	1.57 (1.02 to 2.41)	1.06 (0.66 to 1.71)	
Underlying			0.115
Yes	1.00	1.00	
No	0.96 (0.80 to 1.14)	1.22 (0.95 to 1.57)	
Position			0.011
Supine	1.00	1.00	
Prone	1.28 (0.84 to 1.96)	1.24 (0.76 to 2.00)	
Lithotomy	0.63 (0.46 to 0.86)	1.05 (0.72 to 1.52)	
Lateral	0.37 (0.29 to 0.46)	1.68 (1.13 to 2.52)	
Others	2.86 (1.36 to 6.03)	2.73 (1.21 to 6.15)	

BMI = body mass index; NPO = nothing per oral; CVT = cardiovascular thoracic surgery; ASA = American Society of Anesthesiologists physical status; GA = general anesthesia; TIVA = total venous anesthesia

guidelines that have standardized the anesthetic practice. Moreover, individual hospital policies were also developed to tackle incidences found in each particular center. Thus, the conclusion of the overall hospital in Thailand[1,2] cannot be justified by an individual hospital. Kumhom et al[12] reported that even within the same hospital, adverse incidence were dissimilar indifferent year.

The present study was conducted using incident reporting as a tool to improve the safety and quality of anesthesia in HRH Princess Maha Chakri Sirindhorn Medical Center in order to create a safety culture as mandated in recent global statement[13-15]. Sometimes a person or an organization's routine practice become habit and maybe admitted to prove as a careless act[16]. We created incident report form to reevaluate the clinical routine practice in anesthesia in our institution. All incidents were revised and reiterated by anesthetic personnel or team who managed the situation, to find the contributing factor and possibility of preventive strategy. Thereafter, study team reviewed the incident and finalized the information.

Compared to Thai AIMS and PAAd Thai study there were differences in population being male dominant[1,2]. From incident report, cardiac arrest accounted for 0.1% of total complications in our institute which was less than previous studies[1,2]. Discrepancies were due to large population and diversity across Thailand. Previous multicenter study report focused on critical incidents, while in this study, the author collected and reported all incidents both minor and major. We were able to provide a better representation of the overall picture of events. HRH Princess Maha Chakri Sirindhorn Medical Center had its own factors that contribute to these distinct outcomes.

Previous study found relationship between prolonged fasting time and adverse effect[17,18]. In this data, NPO time had no effect on complications. Interestingly, long operative time increased adverse events, including surgical complications, by 2.5-fold[19].

In this past decade, these has been fewer major complications[2,8] as there are standard practice and guidelines to provide quality assurance[16,3]. However corrective strategies are still needed for minor complications, which account for the majority of adverse events. The limitation of this study was that the adverse events were obtained from a single center study, and in the future this information needs to be kept updated.

Conclusion

The incidence rate of anesthetic complication was 51.64%, most of which (91.61%) were minor adverse events and 65.76% of cases were preventable. The most common complications were hypotension, sore throat, shivering, nausea/vomiting, and dizziness. The factors that

contribute to anesthetic complications are female gender, age >65, pregnancy, long operative time, and positions other than supine. Provided that most of these factors are unmodifiable, anesthetic personnel must stay alert with anesthetic plan and strategy. Patients' condition itself increased chances of morbidity and mortality, while anesthetic risks also partially took part. Factors that minimized the risks were minor operation, TIVA and other anesthesia techniques and supervision. It is important to detect flaws in our routine practice by learning from past events and reconsider our mistakes in order to provide the best practice and raise the standard for patient safety.

What is already known on this topic?

Anesthesia involves many kinds of risks to patients in every process. These risks include minor and major events that increase individual morbidity and mortality rate. With the advance in technology equipment and safety checklist, anesthesia had become a safer practice, but human errors still occurred.

What this study adds?

The minor complications accounted for all 91.61% of the incidence and 65.76% of the incidence were preventable. Factors minimizing the risk were minor operation, TIVA, other anesthesia techniques such as MAC, peripheral nerve block and supervision.

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Potential conflicts of interest

The authors declare no conflict of interest.

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