The Thai Anesthesia Incidents Study (THAI Study) of Anesthetic Equipment Failure/Malfunction: A Qualitative analysis for risk factors

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Background: *Anesthesia equipment problems may contribute to anesthetic morbidity and mortality. In Thailand, the magnitude and pattern of these problems has not been established. We therefore analyzed the frequency, type and severity of equipment-related problems, and what additional efforts might be needed to improve safety.*

Material and Method: *The data were drawn from the Thai Anesthesia Incidents Study (THAI Study) between February 1, 2003 and July 31, 2004 in which anesthesia-related data (*i.e. *of perioperative problems and their severity) were recorded (by the attending anesthesiologist) from all anesthetic cases on a routine basis. We selected cases under general and regional anesthesia with anesthetic equipment failure/malfunction for descriptive analysis.*

Results: *The frequency of anesthetic equipment problems of the 202,699 recorded cases was approximated 0.04% or 1 : 2252. Two-thirds of the problems (63%) involved the anesthesia machine and of these incidents 73 and 41 percent involved system and human errors, respectively. One patient died and one suffered permanent morbidity.*

Conclusion: *The incidence and severity of equipment problems was low. Aside from improvements to pre-operative equipment checks, vigilance, continuous quality improvement and quality assurance activities were suggested as strategies to reduce problems.*

Keywords: *Anesthesia, Complications, Equipment problems, Quality improvement*

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Adverse events related to anesthesia may contribute to morbidity and mortality[1-6]; thus, anesthesia equipment is crucial for the safe conduct of anesthesia. Previous studies indicate that the frequency of equipment problems varies between 0.2 and 2.1%, depending on the study design, method of problem reporting and problem classification[7,8]. In 2003, the Thai Anesthesia Incidents Study (THAI Study) instituted a system for recording data from adverse anesthesia events. We aimed to analyze the frequency, type and severity of equipment-related problems,outcomes, con-tributing factors and corrective strategies from the re-cords of 202,699 consecutive cases between February 1, 2003 and July 31, 2004.

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Material and Method

The THAI Study was an incidence study undertaken by 7 university hospitals, 5 tertiary care hospitals, 4 secondary care hospitals and 4 primary care hospitals. The Institutional Ethical Review Board of each hospital reviewed the study protocols then ap-proved the study. Details of the consecutive patients (regarding their pre-operative data, anesthetic techniques, intra-operative events and complications within 24 postoperative hours) were recorded on a

standardized form (Form 1).

Equipment was defined as: 1) **anesthesia equipment** (*i.e.* medical gas supplies, flow meters, oxygen failure protection, vaporizers, machine/breathing system leakage, machine/breathing system function, ventilator, scavenging suction); 2) **airway equipment** (*i.e.* face mask, endotracheal tube, LMA, laryngoscope); 3) **monitoring equipment** (*i.e.* non-invasive and invasive blood pressure monitor, pulse oximetry, electrocardiography, capnometer, temperature monitor, and intraoperative blood chemistry monitoring); and, 4) **theatre equipment** (*i.e.* infusion pump, theatre table, electricity, blood warmer and warming blanket).

The severity of outcomes was: Grade 1 a small problem with complete recovery or minor physiological change; Grade 2 a problem of moderate difficulty affecting the patient, but with a low severity (*i.e.* prolonged emergence, prolonged apnea, awareness or psychic trauma); Grade 3 a serious situation difficult to handle or that caused a serious deterioration in the patient s status, which may or may not contribute to postoperative morbidity (*i.e.* major physiological change); and, Grade 4 a problem with a fatal outcome (*i.e.* cardiac arrest).

Details of adverse events related to equipment failure or malfunction were recorded by anesthesiologists or nurse anesthetists. Records were reviewed by 3 peer reviewers to identify the clinical risk and contributing factors and strategies for prevention and improvement. Conflicting opinions were reviewed and agreement was judged by the consensus of 3 peer revie-wers. All of the data were analyzed using descriptive statistics.

Results

We reviewed the resulting 90 charts (Form 2) in which anesthetic equipment failure/malfunction. The occurrence of equipment problems was approximately 0.04% or 1 : 2252. The incidents were detected by: anesthesiologists (in 36 cases; 40%), nurse anesthetists

Table 1. Distribution of incidents vis-vis stage of anesthesia

Time of incident	Cases	%
Induction	19	21.1
Intubation	17	18.9
Maintenance	47	52.2
Emergence	4	4.4
Extubation	0	0
Recovery Room	3	3.3
Total	**90**	**100**

Table 2. Type of Equipments involved and severity of problems

Equipment involved	Severity Grade 1 (n)	Severity Grade 2 (n)	Severity Grade 3 (n)	Severity Grade 4 (n)	Total equipment problems n (%)
Anesthesia machine	45	1	**10**	1	57(63.3)
Non-invasive arterial pressure	2				2(2.2)
Monitor blood sugar		1			1(1.1)
Pulse oximetry	6				6(6.7)
Airway equipment	4	1			5(5.6)
Theater equipment	2				2(2.2)
IV access	2				2(2.2)
Laryngoscope	15				15(16.7)
Total	**76**	**3**	**10**	**1**	**90**

Grade 1 = Minor problems
Grade 2 = Moderately difficult problems with some effect to the patient, but low severity
Grade 3 = Serious situation difficult causing a serious deterioration in the patient s state, which may or may not contribute to post-operative morbidity
Grade 4 = Fatal problems

Table 3. Serious effects on the patient caused by equipment problems

Equipment involved	Problem	Effect	n
Anesthesia machine	Misconnection	Hypoxemia	1
	Ventilation problems	Pneumothorax	1
	APL malfunction	High airway pressure	3
	Power supply-ventilator stopped	Hypoxemia	1
	Disconnection at common gas outlet	Hypoxemia	2
	Vaporizer	Awareness,Psychic trauma, Hypoxemia	2
	Sodalime-pancake, leakage from connector to sodalime canister	Hypertension, tachycardia, Hypoxemia	3
	Coaxial circuit kink	High airway pressure	1
	Leakage of inflating bag	Severe hypoxemia, severe bradycardia, CPR	1
	No fail-safe device	Dead	1
Pulse oximetry	Non detect	Hypoxemia	1
Monitor blood sugar	Over measure	Severe hypoglycemia	1
Airway equipment	Obstruction of LMA opening	Increase airway resistance	1
Total			**19**

Table 4. Management of equipment problems

Management	n	%
Cancel / postpone surgery	0	0
Supportive treatment	43	47.8
Repair the equipment immediately	67	74.4
Change the equipment	46	51.1
Incidence reporting	4	4.4
Unplanned Hospitalization	1	1.1
Unplanned ICU admission	1	1.1
Prolonged Hospital Admission	0	0

(34 cases; 37.8%), anesthesia residents (7 cases; 7.8%) and not stated (12 cases; 15%). The majority of events occurred during maintenance (47 cases; 52.2%), induction (19 cases; 21.1%) and intubation (17 cases; 18.9%) (Table 1).

Most equipment problems were trivial (severity grade 1) (Table 2). Ten problems were serious (Grade 3) and only one was fatal. Two-thirds of the problems (63.3%) occurred with the anesthetics machine including: common gas outlet (in 11 cases; 19.3%), ventilator (10 cases; 17.5%), unidirectional valve (9 cases; 15.8%), carbon dioxide absorber (5 cases; 8.8%), vaporizer (6 cases; 10.5%), pressure relief valve (3 cases; 5.3%), overpressure (2 cases; 3.5%), flow meter (2 cases; 3.5%), disconnection (2 cases; 3.5%), re-breathing (1 cases; 1.8%), breathing bag (1 case; 1.8%), scavenging system (1 case; 1.8%) and others (3 cases; 5.3%).

Airway equipment failure was related to the laryngoscope (in 15 cases; 75%), the endotracheal tube (4 cases; 20%), and the laryngeal mask airway (1 case; 5%). Monitoring problems occurred in 9 cases: 6 from pulse oximetry, 2 from non-invasive blood pressure monitoring, and 1 from another problem. Theatre equipment failure was related to intravenous apparatus (in 2 cases), warmer blanket (1) and one from burst suction apparatus. Serious effects related to equipment problems were presented in Table 3.

The majority of cases were managed by repairing the equipment (in 67 cases; 74.4%), changing the equipment (46 cases; 51%) or supportive treatment to the patients (43 cases; 47.8%) (Table 4). Within 24 hours of the events, most of the patients had completely recovered though 10 experienced major physiological changes (*i.e.* 2 cardiac arrest and 1 awareness). Twenty-four hours to 7 days after the events, one patient had died and another patient had psychic trauma. We had no cases of disability, vegetative or brain death (Table 5).

Anesthesia was considered the sole contributing factor in 89 cases (98.9%) and in combination with a patient s problem in only 1 case (1.1%). All incidents were thought preventable. Considering a holistic analysis, the three most important contributing factors included system factors (66 cases; 73.3%), human error

Table 5. Immediate outcome and long-term outcome within 7 days of anesthesia

Outcome	Immediate outcome n (%)	Long term outcome n (%)
Complete recovery	69 (76.7)	88 (97.8)
Major physiological change	10 (11.1)	0 (0)
Minor physiological change	7 (7.7)	0 (0)
Cardiac arrest	2 (2.2)	0 (0)
Awareness	1 (1.1)	0 (0)
Prolonged emergence/prolonged apnea	1 (1.1)	0 (0)
Death	0 (0)	1 (1.1)
Psychic trauma	0 (0)	1 (1.1)

Table 6. Contributing factors

Factors	n	%
Human factors	37	41.1
1. Inadequate anesthesiologists	0	
2. Inappropriate decision making	1	
3. Lack of knowledge	1	
4. Haste	7	
5. Fatigue	1	
6. Inadequate experience	0	
7. Communication failure	0	
8. Unacquainted environment	1	
9. Improper preoperative checking of Equipment	26	
System factors	66	73.3
1. Inadequate & inefficient equipment	63	
2. Lack of maintenance system	61	
3. Lack of guideline practice	0	
Patient factors	2	2.2

(37 cases; 41.1%) and patient factors (2 cases; 2.2%) (Table 6).

The majority of reports with proposed corrective strategies suggested the need for greater vigilance (71.1%), continuous quality improvement (71.1%), quality assurance activities (66.6%) and continuous equipment maintenance (60%) (Table 7).

Discussion

The incidence of equipment failure/malfunction in THAI Study was rare (4.4 in 10 000) and of a low severity. The low frequency of equipment problem is similar to a study by Fasting and Gisvold (2002) who reported that 0.05% in regional anesthesia and 0.23% in general anesthesia [8], whereas Webb *et al*. (1993) reported a higher incidence of 9%[9]. However, the incidence might be low due to under-reporting because most problems were minor mistakes, which obscured working but did no harm to the patients. Nevertheless, the analysis of patterns and causes of these problems are of use when planning quality assurance activities.

Our results indicate that no serious morbidity occurred in 97.8% of the patients; thus, a tiny minority had severe morbidity and mortality. One patient had severe bradycardia and hypoxemia because of leakage of the flow inflating bag and esophageal intubation. He recovered because of prompt cardiopulmonary resuscitation and a bag change after re-intubation.

Table 7. Minimizing factors and suggestedcorrective strategies

Minimizing factors and corrections	Cases	%
Prior experience	14	15.5
Experienced supervisor	3	3.3
High vigilance	64	71.1
More man power	0	0
Efficient consultation system	0	0
Improve communication	0	0
Additional training	2	2.2
Adequate equipment	12	13.3
Continuous equipment maintenance	54	60
Continuous equipment checking	64	71.1
Practice guideline	9	10
Quality assurance activity	60	66.6

Another patient died postoperatively because of a combination of severe trauma and severe hypoxemia caused by human error and equipment failure. In this case, 100% of nitrous oxide was supplied just after the operation even though the oxygen was turned on because there was no fail-safe system on that anesthetic machine. Our mortality rate (1.1%) was therefore within the range of western studies (0-2%) [8,10].

Among equipment problems, the anesthetic machine and gas delivery system were most often involved (63.3%), whereas airway equipment and monitoring problems occurred less frequently (22.2 and 10 percent, respectively) (Table 2). Comparing these findings with other studies, problems from anesthetic machine varied between 25 and 60 percent [8,9,11] airway equipment 30% [11], and monitoring 24% [9,11].

Human error is the primary cause of reported adverse anesthetic events[12-17] and 82% were preventable[18]. Human error in our study (41.1%) was more than in the studies by Cooper (22%) [18] and Fasting (25%)[8]. In order to reduce the possibility of human error causing equipment problems, a three-level approach has been suggested: 1) equipment should be designed so that the possibility of human error is minimized; 2) if human error cannot be prevented, the system should be designed to minimized the injury caused by such errors; 3) the system should be equipped with monitors and alarms to alert the user of an adverse condition occurring because of equipment failure or change in the patient s condition [8].

The most frequent contributing factors were also due to system failure (73.3%), which included inadequate equipment supply and lack of maintenance system. Therefore, practice guidelines development, equipment checking and continuous maintenance to achieve an international standard and adequate equipment supply with efficient monitors and alarm system including continuous quality improvement should minimize the frequency and severity of the adverse events [19-20].

The protection of patients from equipment malfunction depends on: 1) appropriate application of standards set by a national standards association; 2) careful evaluation of equipment prior to purchase; 3) comprehension of equipment function by the user; 4) conscientious routine servicing of all systems concerned with anesthesia, and checking after service and before clinical use; 5) pre-anesthesia testing of equipment, including the use of an oxygen analyzer in the breathing circuit; 6) early inclusion of equipment malfunction in the differential diagnosis of events during anesthesia; and, 7) rapid action that corrects the apparatus malfunction and ***not*** exposing the patient to a new hazard.

In conclusion, adverse events caused by anesthesia equipment failure/malfunction was 0.04% and of a low severity. Anesthetic machines and gas delivery were the most common causes while system failure was the most frequent contributing factor

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อุบัติการณ์เกิดปัญหาเกี่ยวกับเครื่องมือระหว่างการให้ยาระงับความรู้สึกในประเทศไทย : การวิเคราะห์ปัจจัยเสี่ยง

ศิริลักษณ์ กล้าณรงค์ ,วราภรณ์ เชื้ออินทร์ , อักษร พูลนิติพร ,วิโรจน์ เพ่งผล

หลักการและเหตุผล: *อุบัติการณ์เจ็บป่วยและเสียชีวิตที่เกี่ยวข้องกับการให้ยาระงับความรู้สึก สาเหตุส่วนหนึ่งเกิดจากอุปกรณ์และเครื่องมือที่ใช้ในงานวิสัญญี ในประเทศไทยยังไม่มีการศึกษาปัจจัยที่เกี่ยวข้องอย่างจริงจัง ดังนั้นกลุ่มวิจัยจึงได้ทำการศึกษาความถี่ ชนิด และความรุนแรง เพื่อพัฒนางานบริการด้านวิสัญญี*

วัสดุและวิธีการ: *ศึกษาข้อมูลผู้ป่วยที่เกิดปัญหาจากอุปกรณ์และเครื่องมือที่ใช้ในงานวิสัญญีไม่ทำงาน ก่อน ระหว่างและหลังการให้ยาระงับความรู้สึกซึ่งคัดเลือกมาจากข้อมูลการศึกษาของราชวิทยาลัยวิสัญญีแพทย์แห่งประเทศไทยซึ่งรวบรวมตั้งแต่ 1 กุมภาพันธ์ พ.ศ. 2546 ถึง 31 กรกฎาคม พ.ศ. 2547 นำมาวิเคราะห์ทางสถิติเชิงพรรณนา*

ผลการศึกษา: *เกิดอุบัติการณ์จากอุปกรณ์และเครื่องมือที่ใช้ในงานวิสัญญีไม่ทำงาน ประมาณร้อยละ 0.04 หรือ 1:2252 เกิดจากการให้ยาระงับความรู้สึกแบบทั่วไป (ร้อยละ0.08) มากกว่าแบบทำให้ชาเฉพาะส่วน (ร้อยละ0.004) สองในสามของปัญหาเกิดจากเครื่องวางยาสลบ(ร้อยละ63)ในจำนวนนี้มีสาเหตุจากความผิดพลาดในระบบและการประมาทของบุคลากรคิดเป็นร้อยละ 73 และ41 ตามลำดับ มีผู้ป่วย 1 รายเสียชีวิตและอีกรายมีการบาดเจ็บถาวร*

สรุป: *อุบัติการณ์และความรุนแรงจากปัญหาของอุปกรณ์และเครื่องมือที่ใช้ในงานวิสัญญีไม่ทำงานน้อยมาก การตรวจสอบอุปกรณ์อย่างมีระบบและละเอียดรอบคอบ การมีความต่อเนื่องของระบบประกันคุณภาพจึงจะสามารถลดปัญหาดังกล่าวได้*