นิพนธ์ต้นฉบับ • Original Article

ปัญหาที่เกิดจากอุปกรณ์บริหารยาดมสลบ ในขณะระงับความรู้สึกแก่ผู้ป่วย ในโรงพยาบาลศรีนครินทร์ มหาวิทยาลัยขอนแก่น

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ภาควิชาวิสัญญีวิทยา คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น

Inhaled Anesthetic Delivery System Problems During General Anesthesia at Srinagarind Hospital, Khon Kaen University

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หลักการและวัตถุประสงค์: ระหว่างการวางยาสลบ ปัญหาที่เกิดจากระบบบริหารยาดมสลบทำงานผิดปกติ อาจทำให้ผู้ป่วยเกิดภาวะแทรกซ้อนจนถึงแก่ชีวิตได้ ดังนั้นการศึกษานี้จึงต้องการศึกษาถึงอุบัติการณ์และความรุนแรงของปัญหาที่เกิดจากระบบบริหารยาดมสลบทำงานผิดปกติ ในโรงพยาบาลศรีนครินทร์ เพื่อหามาตรการและวิธีป้องกันต่อไป

วิธีการศึกษา: เป็นการศึกษาเชิงพรรณนา แบบไปข้างหน้า ที่โรงพยาบาลศรีนครินทร์ คณะแพทยศาสตร์ มหาวิทยาลัยขอนแก่น ผู้ป่วยทุกรายที่มารับการวางยาสลบและผ่าตัดในปี พ.ศ. 2548 ทั้งหมดได้รับการบันทึกลงในแบบบันทึกการวางยาสลบตามปกติ เมื่อพบปัญหาที่เกิดจากระบบบริหารยาดมสลบ ผู้วางยาสลบจะบันทึกปัญหาเบื้องต้นลงในแบบบันทึกการวางยาสลบ และรีบแจ้งผู้ทำการศึกษาทราบ เพื่อทำการบันทึกรายละเอียดลงในแบบบันทึกอุบัติการณ์ จากนั้นนำไปวิเคราะห์อุบัติการณ์และความรุนแรงของปัญหา แจกแจงโดยใช้ร้อยละ

ผลการศึกษา: มีผู้ป่วยมารับการวางยาสลบและผ่าตัด ณ โรงพยาบาลศรีนครินทร์ ในปี พ.ศ. 2548 จำนวน 8,904 คน พบปัญหาที่เกิดจากอุปกรณ์บริหารยาดมสลบ 16 ราย (ร้อยละ 0.18) โดย 1 ใน 3 ของปัญหาเกิดจากเครื่องช่วยหายใจทำงานผิดปกติ ส่วนสาเหตุพบว่า 1 ใน 2 เกิดจากผู้วางยาสลบตรวจสอบเครื่องมือก่อนใช้งานไม่สมบูรณ์ โดยเฉพาะระหว่างการเปลี่ยนผู้ป่วยเพื่อผ่าตัดรายต่อๆ ไป แต่อย่างไรก็ตามไม่เกิดภาวะแทรกซ้อนที่รุนแรงต่อผู้ป่วย

สรุป: พบอุบัติการณ์และความรุนแรงของปัญหานี้ต่ำมาก เนื่องจากมีการตรวจสอบระบบบริหารยาดมสลบก่อนใช้งาน

Background and Objective: During general anesthesia, inhaled anesthetic delivery system problems may contribute to anesthetic morbidity and mortality. The magnitude and pattern of these problems had not been established at Srinagarind Hospital. The objectives of this study are to identify the incidence and severity of common problems of inhaled anesthetic delivery system and find strategies for prevention.

Methods: Prospective, descriptive study at Srinagarind Hospital, Faculty of Medicine, Khon Kaen University. All patients received general anesthesia in the year 2005. Details of anesthetic management in all patients were recorded on the anesthetic charts on a routine basis. When inhaled anesthetic delivery system problems had occurred, the anesthesia provider responsible for the cases wrote a short description of the event on the anesthetic charts and reported to the authors to record more details in the incidence form for further analysis about the incidence and severity.

Results: There were 8,904 consecutive general anesthetic patients in 2005. Sixteen inhaled anesthetic delivery system problems were recorded (0.18 %). One-third of problems involved the anesthetic ventilators. Human error was a contributing factor in a half of the cases. No patient suffered any lasting morbidity.

Conclusions: The incidence of inhaled anesthetic delivery system problems was very low and not severe during the study period. This was probably due to the

ทุกวัน มีการบำรุงรักษาเครื่องมือที่สม่ำเสมอ ร่วมกับมีเครื่องมือเฝ้าระวังที่เพียบพร้อมและทันสมัย แต่อย่างไรก็ตามยังคงมีโอกาสที่จะเกิดปัญหาที่รุนแรงจากความผิดพลาดของผู้วางยาสลบได้ ดังนั้น จึงควรหาวิธีป้องกันเพิ่มเติมเพื่อลดความเสี่ยงดังกล่าวลง เช่น ผู้วางยาสลบต้องตรวจสอบเครื่องมือก่อนใช้งานให้ละเอียดและสมบูรณ์ที่สุด โดยเฉพาะระหว่างการเปลี่ยนผู้ป่วยเพื่อผ่าตัดรายต่อๆ ไป เป็นต้น

improvement in routines for preoperative equipment checks, regular equipment calibration and good monitoring system in our hospital. However, there is still a potential for serious problems and strategies to prevent human error should be implemented. In addition, an improved check between cases should be encouraged to reduce the occurrence of the problems.

Keywords: anesthesia, complications, inhaled anesthetic delivery system

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Introduction

Anesthesia equipment is important for the safe conduct of anesthesia, but equipment malfunction may occur and also contribute to morbidity and mortality.[1-3] The anesthesia machine, which is one part of the inhaled anesthetic delivery system, has most often been involved in equipment-related morbidity during general anesthesia[1,4-7] and this has led to recommend and extensive use of preoperative checklists. Previous studies have shown that the incidence of anesthesia equipment problems vary from 0.2 to 2.1%. However, study design, method of problem reporting, and problem classification have varied. In addition, routines for the preoperative checking of the inhaled anesthetic delivery system has not been specified.[4,5,8-11] In recent studies, although specific preoperative checking of the inhaled anesthetic delivery system was established, the equipment problems were still reported.[12,13] Those studies have shown that anesthesia machine including the breathing system, are the most common cause of equipment problems during general anesthesia.[1,4-6,10-12] Human error and misuse of equipment, however, have to be more common than true equipment failure.[3,5,12] The main cause is insufficient checking before use, especially between cases.[12,14]

At Srinagarind Hospital, as a university hospital, from the early past decade, the anesthesia providers (anesthesiologists and nurse anesthetists) of the Department of Anesthesiology, simply checked the inhaled anesthetic delivery system and other equipment before anesthetizing the patients. There were no guideline or checklists for checking equipment before use and no recording system for anesthesia-related problems. The incidence of equipment problems were presented and passively recorded in the morbidity & mortality conference only. Nowadays, according to the Hospital Accreditation program, we have established a recording system for anesthesia-related problems, including inhaled anesthetic delivery system problems and a systematic guideline and checklists especially for checking the inhaled anesthetic delivery system before use since 2002. We have created a non-punitive attitude towards the occurrence of problems. All cases were recorded, the recording is obligatory and both an anesthetist and a nurse anesthetist were involved in every case. We have used the data actively in the department for problem discussions and risk management (quality control). However, the incidence, severity and causes of, especially in, inhaled anesthetic delivery system problems in our hospital have not been reported.

We conducted this study in order to identify the exact incidence, severity and causes of inhaled anesthetic delivery system problems that we are interested. We would like to study and analyze these data in prospective manner and find out for more preventive strategies that may help us to improve the quality of service.

Methods

This is a prospective, descriptive study, settings at Srinagarind Hospital, Faculty of Medicine, Khon Kaen University. The protocol was approved by Ethical Committee, Khon Kaen University before the study began. Patients underwent surgery under general anesthesia in a year of 2005, were informed and written informed consent in part of the way of anesthesia routines. All of them were recorded

on the anesthetic charts on a routine basis. When inhaled delivery system problems occurred, the anesthesia provider responsible for the cases wrote a short description of the event on the "Remark Field" of the anesthetic charts and reported to the authors to complete the details in the incident form for analysis.

The problem was graded according to severity. Severity "Grade 1" is a trivial problem and no any adverse effect, "Grade 2" is a moderately difficult problem with some effects on the patient, but of a low severity and complete recovery. "Grade 3" is a serious situation that causes a serious deterioration in the patient state. "Grade 4" is a problem associated with a fatal outcome.[12]

About 9,000 general and 2,000 regional anesthetics are given in our hospital each year, and most types of surgery were performed. In our hospital, the anesthesiologist works in cooperation with a qualified nurse anesthetist who has 12 months postgraduate education in anesthesia. Each morning, the nurses did an extensive check of the inhaled anesthetic delivery system and monitoring system according to departmental procedures. This check includes medical gas supplies, flowmeters, oxygen failure protection, vaporizers, machine/breathing system leakage, machine/breathing system function, ventilator, scavenging system, suction, intubation equipment and related monitors. During the study period, all patients were monitored with blood pressure monitor, EKG monitor, pulse oximeter and capnometer. One doctor and three nurses worked as a team to educate all staff on equipment issues, and the department engaged some companies for continuous maintenance or calibration every 6 months.

The incident forms were sorted according to components of the inhaled anesthetic delivery system involved and analyzed by the authors according to frequency, severity and causes. We used the descriptive statistics and presented as number and percentage.

Results

We anesthetized and recorded 8,904 general anesthetic patients in 2005. The age, gender, ASA class, operative condition, type of surgery and duration of anesthesia were presented in Table 1.

Incidence and severity of inhaled anesthetic delivery system problems

As presented in Table 2, inhaled anesthetic delivery system problems were 0.18% (*n*=16) in 8,904 cases of all general anesthetics. Most problems (*n*=11) were trivial (Severity Grade 1). About one-third (*n*=5) were intermediate (Severity Grade 2) and affected the patients to some degree. Hypoxemia was the most frequent effect on patients (*n*=4) but no patient suffered any lasting morbidity or needed prolonged postoperative care (Table 3).

Involved components of inhaled anesthetic delivery system problems (Table 2)

We found that 37.5% (6/16) of the problems occurred during the use of ventilator. The most common problem related to the ventilator was periodic non-function from electronic control unit malfunction (*n*=5), and inadequate tidal volume from using pediatric bellow in adult patient (*n*=1). Other problems included electric power supply failure of anesthesia machine (*n*=2), gas leakage from loose connection and disconnection of breathing circuit (*n*=2), leakage from the canister of CO_2 absorber (*n*=2), leakage from the vaporizer-machine connection (*n*=1), leakage from the torn breathing bag (*n*=1), no connection of gas supplies (*n*=1), and malfunction of the unidirectional valve (*n*=1).

Human error

A half of the problems (8/16) were considered to be related to human error on the part of the users (Table 4). The problems concerned the breathing circuit (*n*=2), CO_2 absorber canister (*n*=2), gas supply (*n*=1), vaporizer (*n*=1), breathing bag (*n*=1) and ventilator (*n*=1). All of them were related to inadequate pre-use checks. Most of these errors occurred when the equipment was checked between cases, rather than at the start of the day. Contributing factors were a change of equipment, such as changes in type of breathing system, vaporizer, bellow of ventilator, type of anesthesia or change of exhausted CO_2 absorber between cases.

Discussion

From prospectively recorded problems in 8,904 cases of general anesthesia, we found inhaled anesthetic delivery system problems to be rare and low in severity. Human

Table 1 Patient characteristics

Characteristics		*n*	%
Age :	0-30 days	106	1.19
	>1-12 months	397	4.46
	>1-6 yr	755	8.48
	>6-12 yr	633	7.11
	>12-65 yr	6,086	68.35
	>65 yr	927	10.41
Gender :	Male	4,222	47.42
	Female	4,682	52.58
ASA class :	I	3,605	40.49
	II	3,741	42.01
	III	1,263	14.18
	IV	250	2.81
	V	45	0.51
Operative condition :	Elective	7,004	78.66
	Emergency	1,900	21.34
Type of surgery:	Cardio-vascular-thoracic surgery	815	9.15
	Ear nose throat surgery	1,289	14.48
	Eye surgery	391	4.39
	General surgery	2,370	26.62
	Neurosurgery	435	4.85
	OB/GYN surgery	1,158	13.01
	Orthopedic surgery	1,233	13.85
	Pediatric surgery	423	4.75
	Others	220	2.47
Duration of anesthesia :	< 1 hr	1,855	20.83
	1-2 hr	3,170	35.60
	> 2 hr	3,879	43.56
Total general anesthetics		**8,904**	**100.00**

Table 2 Involved components of inhaled anaesthetic delivery system and severity of problem

Part involved	Severity				Total problems
	Grade 1	Grade 2	Grade 3	Grade 4	*(n)*
Ventilator	5	1			6
Anesthesia machine					
- Power supply	2				2
Breathing circuit	1	1			2
CO_2 absorber	1	1			2
Gas supply	1				1
Vaporizer		1			1
Unidirectional valve	1				1
Breathing bag		1			1
Total	**11**	**5**			**16**

Table 3 Untoward effects on the patient caused by inhaled anesthetic delivery system problems (Severity Grade≥2)

Equipment involved	Problems	Effect on patients	*n*
Vaporizer	Leakage from the vaporizer-machine connection	Severe Hypoxemia (SpO_2 55%)	1
Breathing circuit	Leakage from inspiratory unidirectional valve-circuit connection	Mild Hypoxemia (SpO_2 92%)	1
CO_2 absorber	Leakage from CO_2 canister	Severe Hypoxemia (SpO_2 67%)	1
Breathing bag	Leakage from breathing bag	Mild Hypoxemia (SpO_2 90%)	1
Ventilator	Pediatric bellow in adult	Hypercarbia ($PaCO_2$ 65 mmHg)	1
Total			5

Table 4 Human error contributing to inhaled anaesthetic delivery system problems

Equipment involved	Problems	*n*
Breathing circuit	Leakage from breathing circuit:	
	- Loose connection between unidirectional valve and inspiratory limb of circle circuit	1
	- Disconnection between unidirectional valve and inspiratory limb of circle circuit	1
CO_2 absorber	Leakage from CO_2 absorber canister	
	- After soda lime change over	1
	- Canister broke from crashing during adjustment the operative table	1
Gas supply	No connection of gas supplies	1
Vaporizer	Leakage from the vaporizer-machine connection after change over	1
Breathing bag	Torn breathing bag	1
Ventilator	Inadequate tidal volume because pediatric bellow was used in adult	1
Total		8

errors are important factors, in addition to 'pure' equipment failure. The low incidence limits its usefulness as a numerical quality indicator. However, analysis of patterns and causes of these problems can be a useful part of a quality assurance program in our department.

Discussion

From the previous studies about incident reporting, under-reporting is a potential problem. This is related to the added workload from completion of forms, a belief that reporting has limited value, and fear of consequences of reporting.[15-18] But in our study, we belief that the reporting compliance was good, because our study is designed to add minimal workload. In addition, we have a non-punitive attitude of problems and all general anesthetic patients were followed and included in the study. The incidents are recorded in a prospective manner and important events are less likely to be missed.

Incidence and severity of inhaled anesthetic delivery system problems

The anesthesia machine, which is one part of the inhaled anesthetic delivery system, has most often been involved in equipment-related morbidity during general anesthesia[1,4-7] and this has led to recommend and extensive use of preoperative checklists. Five studies have been published representing mandatory reporting, with data recorded from all anesthetic cases.[8-11] The incidence of equipment problems were 0.1-0.4% in 27,184 cases, [8] 0.7% in 18,350 cases,[9] 0.9% in 26,907 cases,[10] 1.2% in 96,000 cases[11] and 0.2% in 10,607 cases.[13] However, study design, method of problem reporting, and problem classification

varied, and routines for the preoperative checking of inhaled anesthetic delivery system were not specified.

From the study of Fasting and Gisvold,[12] they have studied about equipment problems recorded from 83,154 cases in 1996-2000, in the University Hospital of Trondheim, Norway, where has already instituted a system for the recording of anesthetic-related data and established a specific preoperative checking of inhaled anesthetic delivery system during general anesthesia, which has the settings similar to our hospital. The incidence of equipment problems of all anesthetic cases was 0.19% (0.05% of regional anesthetics (*n*=20,564) and 0.23% of general anesthetics (*n*=62,590). These problems from anesthesia machine including the breathing system, were the most common cause of equipment problems during general anesthesia (31.21% of equipment problems and 0.08% of general anesthetics). Most problems (92.28%) were trivial (Severity Grade 1) and 2.72% were intermediate in severity (Severity Grade 2) and affected the patients to some degree but no patient suffered any lasting morbidity or needed prolonged postoperative care. In our study, we found that the incidence in general anesthetic cases was low (0.18%) and most problems (68.75%) were trivial and 31.25% were intermediate severity and slightly affected the patients, as similar as the study of Fasting and Gisvold. The low rate and severity of the incidents in our study may result from improvement in routines for preoperative equipment checks, regular equipment calibration and good monitoring system in our hospital.

Involved components of the inhaled anesthetic delivery system problems

We found that the anesthetic ventilator was the most common cause (37.5%) of inhaled anesthetic delivery system problems in our hospital. All were electronic-controlled system. The main problems are periodic non-function from electronic control unit malfunction. These ventilators were often used heavily for a long time per day for many years and this might predispose it to errors, despited the routines for checking them at start of the day and continuous maintenance or calibration them every 6 months. It was different from other studies, in which the anesthesia machine including the breathing system, was the most common cause of equipment problems.[1,4-6,10-12]

Human error

Human error and misuse of equipment have been shown to be more common than true equipment failure.[3,5,12] In our study, human error was the main contributing factor in a half of cases, and these involved many components of the inhaled anesthetic delivery system. The main cause was insufficient checking of it before use, especially between cases. This was also shown by previous studies.[12,14]

To reduce the possibility of human error causing equipment problems, a three-level approach has been suggested: (a) when possible, equipment should be designed such that the possibility of human error is minimized; (b) if human error cannot be prevented, systems should be designed to minimize the injury caused by such errors; (c) if neither of the previous safety approaches is possible, the system should be equipped with monitors and alarms to alert the user of an adverse condition that may be caused by equipment failure or change in the patient's condition.[19,20]

Continuous quality improvement

The low rate of the inhaled anesthetic delivery system problems limits our results to be used as a continuous numerical quality indicator, as changes in occurrence caused by efforts to improve are difficult to separate from natural variation. The low rate of these problems recorded also indicates that our routines for maintenance and checking before use of equipment are quite adequate. However, there is still a potential for serious problems. Therefore, strategies to prevent human error should be implemented as this contributed to a half of problems. In addition, an improved check between cases may reduce the occurrence of equipment problems with the inhaled anesthetic delivery system.

A routine-based recording system will give us the possibility of evaluating problem rates, as the total number of anesthetics is known, but closely surveillance must be taken if the occurrence is rare.

Conclusion

In our checking and maintenance routines, we found the inhaled anesthetic delivery system to cause few problems, the incidence related to number of cases was 0.18%. Human factors were important causes of problems, and the

ventilator problems were most often involved. Although we recorded no morbidity from these problems in 8,904 cases, both this and other studies have indicated that a potential for equipment-related morbidity exists. The type of data retrieved from our analysis provides valuable information for departmental quality improvement projects.

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