The Thai Anesthesia Incident Monitoring Study (Thai AIMS): An Analysis of 21 Awareness Events

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Objective: *To demonstrate the characteristics, outcomes, and the circumstances associated with intraoperative recall of awareness*
Material and Method: *Relevant data of intra-operative recall of awareness were extracted from the Thai Anesthesia Incident Monitoring study (Thai AIMS) database of 1996 incident reports and 2537 incidents which were conducted among 51 hospitals throughout Thailand from January to June, 2007. Details regarding patients, surgical, anesthetic and systematic factors were recorded in a structured data record form. The completed record forms were reviewed independently by three anesthesiologists. The descriptive statistic was analyzed by using SPSS software version 11.5 and demonstrated in number and percent.*
Results: *Twenty-one incidents (21/1996 = 1.05%) of intra-operative recall of awareness were reported. Awareness was predominantly found in females (76.2%) and with ASA physical status I (47.6%). Most of the patients recalled events during the maintenance period and reported sound (71.4%), pain (52.4%), feeling operated (38.1%), paralysis (33.3%), recognizing intubated (4.8%) and panic (4.8%). Anxiety (33.3%), temporary emotional stress (19%), and post traumatic stress (4.8%) were found during immediate outcome assessment but scarcely sustained on the hospital discharged date. The factors associated with the incidents were anesthetic related in the majority especially ineffective monitoring (100%), pre-medication abandonment (100%) and light anesthesia (71.5%).*
Conclusion: *Intra-operative recall of awareness in the Thai AIMS was 1.05% of all incident reports. Most of the events were considered as anesthesia related. The suggested corrective strategies were quality assurance activity, effective monitoring and equipment maintenance.*

Keywords: *Intra-operative, Recall, Adverse event, Awareness, Anesthesia, Complications*

J Med Assoc Thai 2009; 92 (3): 335-41
Full text. e-Journal: *http://www.mat.or.th/journal*

Awareness with recall during general anesthesia is of significant concern to patients. It can be classified both explicit together with implicit memory[1,2]. The information of those episodes may be stored temporarily and experienced in reminiscence function which is associated with significant adverse psychologically consequence, posttraumatic stress disorder[3]. The symptoms included anxiety, insomnia, irritability, repetitive nightmares, depression or even attempted suicide[4]. However, the overall incidence of intra-operative recall of awareness is relatively infrequent and varies among countries as well as the institutions depending on their anesthetic practice, patient features and surgical aspects. In Asia, the data from the THAI Study reported 0.08% among 126,078 general anesthetized cases within 20 hospitals throughout Thailand from February 1st 2003 to July 31st 2004[5,6]. Another study from China studied by Shi et al

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revealed 1.4% of awareness among 2,025 patients who underwent general anesthesia during different kinds of elective operation[7]. In North America, Sebel et al reported an incidence of 0.13% in 19,575 patients treated at 7 academic medical centers in the United States[8]. Even though Pollard et al revealed 0.0068% awareness from 211,842 enrolled[9]. In Europe from Sweden, Sandin et al found 0.18% in cases in which neuromuscular blocking drugs were used while 0.10% in the absence of such drugs[10]. Furthermore in Australia, Myles et al reported an incidence of intra-operative awareness of 0.10% which was the utmost risk factor for patient dissatisfaction after anesthesia[11].

The first large scale prospective cohort study in 20 hospitals across Thailand, namely the Thai Anesthesia Incident Study (THAI Study), was conducted in 2004 including a study of the awareness of recall. The incidence, contributing factors, the appropriateness of event management and the corrective strategies were identified[5,6]. Nevertheless the incident report for the descriptions of awareness in addition to the effectiveness of the existing protective methods was not summarized. The multi-center prospective cohort study of incident reports among 51 hospitals, namely the Thai Anesthesia Incident Monitoring Study (Thai AIMS), was organized by the Royal College of Anesthesiologists of Thailand. The aim of the present sub-study was, therefore, undertaken to determine those characteristics, outcome and the circumstances associated with intra-operative recall of awareness.

Material and Method

The present prospective multi-centered study, a part of the Thai Anesthesia Incident Monitoring Study (Thai AIMS), was conducted by the Royal College of Anesthesiologists of Thailand from January to the end of June 2007. All anesthesiologists and nurse anesthetists in fifty-one hospitals ranging from district (community) hospitals to tertiary hospitals across Thailand were invited to report the critical incidents on an anonymous and voluntary basis.

After being approved by each institutional ethical committee, the specific anesthesia related adverse events detected during anesthesia and during 24 hr postoperative period were reported by filling out a standardized incident reporting form as soon as possible after occurrence of adverse or undesirable events. 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/cerebrovascular 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.

Intra-operative recall of awareness is defined as unexpected, undesirable patient sensation of wakefulness during general anesthesia and the subsequent conscious recollection of those events between the induction of anesthesia and recovery of consciousness at the end of anesthesia[5,6,12]. In addition, whether the decision of the correspondent was intra-operative awareness of recall diagnosed or undetermined, the patients would be structurally interviewed by both the close-end and open-end questionnaire during the first 24 hours of anesthesia and the day of discharge for long term outcome. The details regarding demographic data, contributing factors, suggestive corrective strategies and emphasizing on possible patients factors, *i.e* hemodynamics, predisposing personality, usage of other drug affected anesthesia; surgical factors, *i.e* type of the operation, procedure; anesthetic factors, *i.e* pre-anesthetic condition, anesthetic techniques, level of anesthesia, intra-operative monitoring, agents; and systematic factors, *i.e* experience of anesthesia care providers, emergency and admission categorized were identified and completed as well as the descriptions of awareness, *i.e* period of occurrence, character, immediate and discharge outcome.

The collected incident report of awareness during general anesthesia was reviewed by the awareness committee members. Any controversy was discussed to achieve a consensus and if necessary, an expanded committee or additional information was requested. Each incidence was known by a unique identification number to which only the correspondent and the project manager could access. The descriptive statistics was analyzed by using SPSS software for Window version 11.5 and demonstrated in number and percentage.

Results

There were 23 incident reports of suspected awareness during anesthesia from the database of 1996 incident reports of the Thai AIMS. Only 21 cases (1.05% of all incident reports) were considered as awareness during general anesthesia according to definition. The majority of the incidents occurred in females (76.2%) with a mean age of 43.0 $\pm$ 14.2 years. The average body

mass index and duration of anesthesia were 22.8 ± 2.7 $kg.m^{-2}$ and 105.2 ± 52.3 min respectively. Among 21 patients who experienced awareness, the American Society of Anesthesiologists (ASA) physical status of 1, 2, 3, 4 and 5 are 47.6%, 28.6%, 19.0%, 4.8% and 0% respectively.

Most of the awareness arose in the maintenance period (95.2%) with the auditory perceptions (71.4%) and perception of pain (52.4%), there were no symptoms affected for immediate outcome (42.8%) or the discharge outcome (66.7%). The descriptions of intra-operative awareness of recall in general and individually are shown in Table 1 and 2 respectively.

After reviewing the data records of 21 incidents, these were considered that anesthetic related was a vast majority, accentuated on the effectual anesthetic monitoring deficiency (100%) and the abandonment of pre-medication (100%). Obviously all of the patients experienced awareness had the combination at least 2 from 3 main related factors. The factors related to awareness are demonstrated in Table 3.

On the subsection of the contributing factor aspects, 57% of cases were caused by inappropriate decision making, 24% of cases had knowledge incompetent as well as indelicate manner, and 19% of cases had scarce proficiency. The suggestive corrective strategies were recommended in Table 4.

Table 1. Characteristics of awareness and outcomes (n = 21)

	Number	Percent
Period of occurrence		
Induction and intubation	1	4.8
Maintenance	20	95.2
Emergence	0	0
Character		
Auditory perception	15	71.4
Pain remembrance	11	52.4
Feeling operate without pain	8	38.1
Being unable to move	7	33.3
Sensation of the endotracheal tube	1	4.8
Panic	1	4.8
Immediate outcome		
No symptoms	9	42.8
Anxiety	7	33.3
Temporary emotional stress	4	19.0
Posttraumatic stress disorder	1	4.8
Discharge outcome		
No symptoms	14	66.7
Fear of surgery	2	9.5
Fear of anesthesia	2	9.5
Anxiety	1	4.8
Sleep disturbance	1	4.8
Temporary emotional stress	1	4.8

Values shown as number (%)

Discussion

Incident reporting of the infrequent or adverse events has been accepted widely as one of a variety tool for quality assurance program. This scheme can be utilized as a reasonable data for comparing and benchmarking between each hospital. Additionally it will empower the medical personnel to realize which events are critical and need attention for preventive strategy[13].

The reporting paradigm of the undesirable incidents which the authors selected in the present study was the voluntary reporting approach. It is relatively practicable, economical and enables capturing some omitted beneficial information. However, regarding technique it is probably created under reporting attributable to the likelihood of professional jeopardy. Hence, the authors designed this anonymous system and only to demonstrated its significance. Furthermore, the authors formulated as an educational method, not a liability so as in supported by intensive motivation to facilitate the completeness of data recording.

Auditory perception during anesthesia was described to be the most common type of perception[1,14]. The others denoted dream, pain sensation and anxiety by means of this observation[7,8,10,15]. The physiological and emotional symptoms aftereffect was dissolved as a minimum at discharged date. Nonetheless, the follow-up should be obtained in at least 3-4 weeks otherwise the extremely adverse sequelae, post traumatic stress syndromes diagnosed might be overlooked[3,4].

Several factors can increase the risk of intra-operative awareness. The prospect of circumstances which the authors have noticed was comparable to previous studies. Those factors included light anesthesia, some types of surgery, chronic use of central nervous system depressants, obesity, younger age, the absence of pre-medication, inadequate or misused anesthetic delivery system, insufficient knowledge and ignoring monitor usage[16,17]. Shi et al demonstrated that significant factors associated with awareness were intra-operative blood pressure fluctuation [OR 10.43 (95% CI 1.25-7.63)] and female gender [OR 2.86 (95% CI 1.81-6.81)][7]. Nonetheless some reports were dissimilar *i.e* Wennervirta et al

Table 2. The descriptions of individual awareness incidents (n = 21)

Sex/age	ASA	Operation	Anesthetics	Description
M/50	4	General	Etomidate, fentanyl, nmb	Auditory perception, surgery without pain, felt paralyzed
F/60	1	Orthopedic	N_2O, propofol, isoflurane, morphine, nmb	Auditory perception, surgery without pain
F/45	1	Gynecological	N_2O, propofol, sevoflurane, morphine, nmb	Auditory perception, surgery with pain
M/77	2	Orthopedic	N_2O, etomidate, sevoflurane, fentanyl, nmb	Felt paralyzed, surgery without pain
F/24	2	Obstetric	Propofol, nmb	Felt intubated
F/50	1	General	N_2O, propofol, sevoflurane, fentanyl, nmb	Auditory perception, surgery with pain, felt paralyzed
F/26	2	Cardiac	Penthotal, midazolam, sevoflurane, fentanyl, morphine, nmb	Surgery with pain, felt paralyzed
F/45	2	General	Propofol, isoflurane, fentanyl, nmb	Auditory perception, surgery with pain
F/44	1	General	Propofol, sevoflurane, fentanyl, nmb	Surgery with pain, felt paralyzed
F/55	2	Orthopedic	N_2O, penthotal, isoflurane, fentanyl, nmb	Anxiety
M/26	1	Orthopedic	N_2O, propofol, midazolam, diazepam, morphine, nmb	Auditory perception, surgery without pain
F/31	1	Laparoscopic	N_2O, propofol, midazolam, sevoflurane, fentanyl, nmb	Surgery with pain
F/34	2	Obstetric	Penthotal, desflurane, fentanyl, morphine, nmb	Auditory perception, surgery with pain
F/33	3	Gynecological	Penthotal, midazolam, sevoflurane, morphine, nmb	Auditory perception, surgery with pain
F/32	1	General	Penthotal, sevoflurane, fentanyl, nmb	Auditory perception, surgery without pain
F/33	1	Obstetric	N_2O, penthotal, sevoflurane, fentanyl, nmb	Auditory perception, surgery with pain
M/62	3	General	N_2O, propofol, midazolam, isoflurane, fentanyl, nmb	Surgery with pain
F/40	1	Gynecological	N_2O, propofol, fentanyl, nmb	Auditory perception, surgery without pain, felt paralyzed
F/28	1	Obstetric	N_2O, propofol, isoflurane, morphine, nmb	Auditory perception, surgery without pain
F/37	3	Cardiac	Propofol, midazolam, isoflurane, fentanyl, nmb	Auditory perception, surgery with pain, felt paralyzed
M/55	3	General	N_2O, propofol, isoflurane, fentanyl, nmb	Auditory perception, surgery without pain

ASA = American society of anesthesiologists physical classification, nmb = neuromuscular blocking agents

Table 3. Factors related to awareness (n = 21)

Factors	Number	Percent
Patient associated		
Hemodynamic instability	4	19.0
Predisposing personality	3	14.3
Usage of other drug affected anesthesia	3	14.3
Hypermetabolic state	2	9.5
Surgical associated		
General surgery	7	33.3
Obstetric and gynecological surgery	7	33.3
Orthopedic surgery	4	19.0
Cardiac surgery	2	9.5
Endoscopic surgery	1	4.8
Anesthetic associated		
Ineffective monitoring	21	100
Premedication abandonment	21	100
Light anesthesia	15	71.5
Systematic associated		
Inexperience of anesthetic care providers	6	28.6
Admission categorization		
Outpatient : Inpatient	5:6	23.8:76.2
Emergency categorization		
Elective surgery : Emergency surgery	14:7	66.7:33.3

Table 4. The suggestive corrective strategies for depreciate awareness incidence

	Number	Percent
Quality assurance activity	17	80.9
Effective monitoring	4	19.0
Equipment maintenance program	3	14.3
Improved supervision	2	9.5
Clinical practice guidelines	1	4.8

indicated that outpatients were not at increased risk for awareness compared with inpatients under the assumption of two times difference for the incidence in addition with the respect to the administration of muscle relaxants[14]. Although the deteriorating patients have been suggested as risk factors[8], surprisingly the authors found more awareness incidence among the patients with ASA physical status 1-2. The possible explanations were different geographic locations, the patient's variability, differences in anesthetics, and different interview techniques.

During anesthesia, many conventional clinical monitoring modalities are ineffective and undetermined in detecting the awareness possibility even the blood pressure, heart rate, tearing response, and also the patients' movement. Depth of anesthesia monitor has been becoming widely utilized in anesthetic practice worldwide. Electro-encephalogram basis and its data processing to provide the index are the most thoroughly used of which the clinical significant evidences showed the outcome improvement, reducing the incidence of intra-operative awareness, reducing the average amount of administered anesthetics, and enhancing post-anesthetic recovery as well[18-22]. Recently, some studies mentioned about the cost effectiveness for the Bispectral index monitoring, the cost in Australia is 16 USD per use while the cost of preventing one case of intra-operative awareness in high risk patients is about 2,200 USD with the number of 138-861 patients would need to be monitored to avoid one patient suffering from that occurrence[10,19]. However, the 'Routine' Bispectral index monitoring as part of a standard practice should be thoroughly considered because of some clinical debate[23].

Concerning the suggested corrective strategy, the foremost reasons of awareness incidence were probably preventive. The aspects of human errors diminished remarkably on knowledge based and skill based should be exploited. The quality assurance activity for instance, Morbidity and Mortality Conference, Quality Meeting or Risk Management

Protocols would be the superlative and feasible options.

In conclusion, 21 incidents (1.05% of all incident reports) of intra-operative recall after general anesthesia were considered as anesthesia related. The majority of contributing factors was ineffective monitoring, no pre-medication and light anesthesia. Quality assurance activity, effective monitoring and equipment maintenance were suggested corrective strategies.

Acknowledgements

The study was part of the Thai Anesthesia Incident Monitoring Study (Thai AIMS) of anesthetic adverse outcomes which was financially supported by the Royal College of Anesthesiologists of Thailand and National Research Council. The authors wish to following persons namely: Professor Pyatat Tatsanavivat, Khon Kaen University, head of Clinical Research Collaborative Network (CRCN) (for academic support); Mr. Wasan Punyasang and Mr. Nirun Intarut (for data management). We also wish to thank all attending anesthesiologists and nurse anesthetists together with the heads of all 51 departments of Anesthesia who participated in this study.

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การศึกษาภาวะแทรกซ้อนทางวิสัญญีในประเทศไทยโดยการรายงานอุบัติการณ์: การวิเคราะห์อุบัติการณ์ภาวะรู้ตัวระหว่างผ่าตัด 21 ราย

ภูพิงค์ เอกะวิภาต, พิมพ์วรรณ สุขปลั่ง, พรเทพ เปรมสำราญ, ปฏิภาณ ตุ่มทอง, ชัยพฤกษ์ กุสุมาพรรณโญ, พัชรินทร์ หมื่นสายญาติ

วัตถุประสงค์*: เพื่อศึกษาลักษณะผลลัพธ์และบริบทของการเกิดภาวะรู้ตัวระหว่างผ่าตัดจากรายงานอุบัติการณ์*
วัสดุและวิธีการ*: ศึกษาอุบัติการณ์ภาวะรู้ตัวระหว่างผ่าตัดจากฐานข้อมูลของโครงการศึกษาภาวะแทรกซ้อนทางวิสัญญีในประเทศไทย โดยการรายงานอุบัติการณ์ ซึ่งเก็บข้อมูลจากโรงพยาบาลระดับต่าง ๆ ทั่วประเทศ 51 โรงพยาบาล ระหว่างเดือนมกราคมถึงมิถุนายน พ.ศ. 2550 รายงานอุบัติการณ์ประกอบด้วยข้อมูลเกี่ยวกับผู้ป่วย ข้อมูลด้านศัลยกรรม ข้อมูลการให้ยาระงับความรู้สึกและข้อมูลเชิงระบบ ซึ่งได้รับการทบทวนวิเคราะห์โดยวิสัญญีแพทย์ 3 คน ใช้สถิติแบบพรรณนา*
ผลการศึกษา*: พบรายงานอุบัติการณ์ภาวะรู้ตัวระหว่างผ่าตัด 21 ราย ร้อยละ 76.2 ของรายงานพบในหญิง ร้อยละ 47.6 เป็นผู้ป่วย ASA physical status 1 ส่วนใหญ่ของอุบัติการณ์เกิดในช่วงระหว่างการผ่าตัดโดยร้อยละ 71.4 ร้อยละ 52.4 ร้อยละ 38.1 ร้อยละ 33.3 ร้อยละ 4.8 และร้อยละ 4.8 รายงานว่าได้ยินเสียง รู้สึกเจ็บ รู้สึกว่ากำลังถูกผ่าตัด รู้สึกขยับตัวไม่ได้ จำได้ว่ากำลังถูกใส่ท่อหายใจ และรู้สึกกลัวตามลำดับ ผลลัพธ์ระยะแรก ได้แก่ รู้สึกวิตกกังวล ร้อยละ 33.3 เกิดความเครียดทางอารมณ์ ร้อยละ 19 และเกิดภาวะเครียดหลังเหตุวิกฤตร้อยละ 4.8 โดยไม่เกิดผลเสียระยะยาวปัจจัยที่เกี่ยวข้องได้แก่ การเฝ้าระวังที่ไม่มีประสิทธิภาพ (ร้อยละ 100) การไม่ได้ยา pre-medication (ร้อยละ 100) และการได้ยาระงับความรู้สึกระดับตื้น (ร้อยละ 71.5)*
สรุป*: ภาวะรู้สึกตัวระหว่างผ่าตัดพบร้อยละ 1.05 ของจำนวนอุบัติการณ์ทั้งหมดของฐานข้อมูล ซึ่งส่วนใหญ่เกี่ยวข้องกับปัจจัยทางวิสัญญีแนวทางที่แนะนำ ได้แก่กิจกรรมประกันคุณภาพ การเฝ้าระวังมีประสิทธิภาพ และการบำรุงรักษาเครื่องมือที่เกี่ยวข้องกับการให้ยาระงับความรู้สึก*