Predictors of Intra-operative Recall of Awareness: Thai Anesthesia Incidents Study (THAI Study): A Case-Control Study

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Background: *The authors determined predictors of intra-operative recall of awareness in the Thai Anesthesia Incidents Study (THAI Study).*
Objective: *To study a multi-centered registry of anesthesia in 20 hospitals across Thailand.*
Material and Method: *Structured data collection forms of patients who underwent general anesthesia and experienced intra-operative recall of awareness between March 1, 2003 and February 28, 2004, were reviewed by three independent anesthesiologists. One case of awareness was matched to four controls by age, gender, and level of hospitals. Univariate analysis ($p < 0.1$) and logistic regression ($p < 0.05$) identified characteristics associated with intra-operative recall of awareness.*
Results: *Eighty-one cases were matched with 324 controls in the nested case control study. From univariate analysis, risk factors were cardiac surgery, cesarean delivery, upper abdominal surgery, IV anesthetics, depolarizing muscle relaxant, non-depolarizing muscle relaxant, and nitrous oxide ($p < 0.1$). The predictors from multivariable logistic regression were cesarean delivery $p < 0.001$, OR 6.48 (95% CI 2.03, 20.71), and cardiac surgery $p < 0.001$, OR 10.37 (95% CI 3.37, 31.89). Decreased risk was associated with intra-operative use of nitrous oxide $p = 0.02$, OR 0.42 (95% CI 0.20, 0.88).*
Conclusion: *In the THAI Study, predictors of intra-operative recall of awareness were cesarean delivery and cardiac surgery. Use of nitrous oxide attenuates the risk of awareness.*

Keywords: *Awareness, Recall, Anesthesia, Complication, Risk factors*

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Intra-operative recall of awareness is defined as an unexpected and undesirable patient wakefulness during general anesthesia, and the subsequent conscious recollection of events, feelings, or sensations specific to that period[1]. The reported incidence of intra-operative recall of awareness varied from 0.1% to 1.5%[2-8]. Although intra-operative recall of awareness occurred infrequently, it was the highest risk factor for patient dissatisfaction after anesthesia[9] and might greatly affect the well-being of the patients. Previous studies and case reports suggested that certain patient characteristics[8,10-14], surgical procedures[3-5,8,11,14-26], as well as anesthetic techniques[3,6-7,12,15,18,27-30] might be associated with intra-operative recall of awareness.

The present study was aimed to determine the risk factors of intra-operative recall of awareness using the database of the Thai Anesthesia Incidents

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Study (THAI Study) hosted by the Royal College of Anesthesiologists of Thailand.

Material and Method

The Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes was a prospective multi-center registry of consecutive anesthetic performed in 20 hospitals, seven university hospitals (Chiang Mai University, Chulalongkorn University, Siriraj Hospital and Ramathibodi Hospital, Pramonkutklao Medical College, Prince of Songkhla University), five tertiary hospitals (Buddhachinaraj Hospital, Ratchaburi Hospital, Nakorn Sri Thammarat, Khon Kaen Hospital and Neurological institute), four general hospitals (Lampoon Hospital, Pichit Hospital, Baanpong Hospital and Trang Hospital), and four district hospitals (Sanpatong Hospital, Nakorn-Thai Hospital, Kranuan Hospital and Nampong Hospital) across Thailand. The THAI study was approved by all institutional ethical review boards without additional written informed consent needed.

For each patient undergoing a surgical procedure, an anesthesiologist or nurse anesthetist completed a preplanned structured data entry form 1 (form 1), which included a series of patient-related, surgical related and anesthesia related variables. Anesthesiologists or nurse anesthetists used form 1 in addition to the usual anesthetic record. Before starting the present study, several meetings were held to determine the items that would be included and to set definitions for the variables. Workshops and internal audit were held to acquaint the anesthesia personnel with form 1. This form was piloted in six university hospitals before adoption at the other sites with a 1 month run-in period before recruitment of each site in the registry. The present study as part of the THAI study, confined to patients receiving spinal anesthesia only. For the recording of patient related variables, the attending anesthesia personnel were requested to fill in preoperative medical conditions, the American Society of Anesthesiologists physical status classification, and demographic characteristics of the patients. Regarding the surgical procedures, the operations were recorded by converting the written operative procedure into groups of sites of operations. The factors relating to anesthesia including monitors, main anesthetic technique, additional anesthetic technique employed, airway equipment, status of performed of anesthesia, and drug utilized were recorded.

For in-patients, within 24 hr after the surgical procedure, the anesthesia personnel or research nurses visited the patients to record 24 hr anesthesia related adverse outcomes. For out-patients, however, follow-up of all patients was not possible. The adverse outcomes of cardiac arrest, death, total spinal block, nerve injuries, transfusion mismatch, seizure or convulsion, suspected myocardial ischemia or infarction, interested pulmonary complications including desaturation (SpO_2 ≤ 85 or ≤ 90 for more than 3 min), anaphylaxis/anaphylactoid reaction, drug error, and intra-operative recall of awareness were recorded.

Whenever the adverse events of interest occurred, the details of events were recorded in events specific data entry form (form 2). For purposes of analysis, timing of adverse events was divided into two periods, intra-operative period, and within 24 hr after the end of operation.

All forms were reviewed by research nurses or site managers for completeness. Corrections were then made by each center including the verification of the major event recorded. Incompleteness after this step will be considered as missing.

Data collection and analysis

Every form 1 from each hospital during a 12-month period between March 2003 and February 2004 was keyed in at the data management centre at Chulalongkorn University with double-entry technique to ensure the reliability of the database. Every form 2 (adverse events specific form) was reviewed by three independent senior anesthesiologists from different institutions. Disagreement among the three members were discussed and judged to achieve a consensus.

The subjects in this nested case-control study were patients with intra-operative recall of awareness during the one year study period. The authors matched four controls to each case by age, gender, and level of hospital. Risk factors were categorized into patient, surgical, and anesthetic factors. The patient factors included ASA physical status. The surgical factors included the type and site of surgery. The anesthetic factors included pre-medication and drugs utilized.

Descriptive statistics were used to describe the data. Comparisons between cases and controls were conducted with Mantel-Haenszel Chi-square tests. Conditional logistic regression models (Stata version 8.1) were used to determine association of risk factors with intra-operative recall of awareness. Variables found to be significant on univariate analysis (p-value < 0.10) were entered into forward-selection multivariate model. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. A p-value < 0.05 was considered significant.

Table 1. Characteristics of cases and matched controls of intraoperative recall of awareness

	Cases (n = 81)	Controls (n = 324)
Sex		
Male	30 (37)	120 (37)
Female	51 (63)	204 (63)
Age		
< 12 years old	0	0
12-65 years old	79 (88.9)	316 (88.9)
> 65 years old	2 (11.1)	8 (11.1)
Range (years)	18-81	18-81
Level of hospital		
University hospital	58 (71.6)	232 (71.6)
Regional hospital	19 (23.5)	76 (23.5)
General hospital	4 (4.9)	16 (4.9)
District hospital	0	0

Values are numbers (percentages) unless stated otherwise

Table 2. Characteristics of cases and controls of intra operative recall of awareness (univariate)

	Cases (n = 81)	Controls (n = 324)	p-value
Patient factor			
ASA Physical status			
1-2	68 (84.0)	275 (84.9)	
3-5	13 (16.0)	49 (15.1)	0.84
Surgical factors			
Type of surgery			
Elective	52 (64.2)	221 (68.2)	
Emergency	29 (35.8)	103 (31.8)	0.46
Site of surgery			
Cardiac	19 (23.5)	7 (2.2)	0.00
Lower abdominal including kidney/ureter	16 (19.8)	79 (24.4)	0.38
Cesarean delivery	11 (13.6)	19 (5.9)	0.01
Extremities	7 (8.6)	37 (11.4)	0.47
Lumbosacral spine	4 (4.9)	14 (4.3)	0.81
Perineal-anal	4 (4.9)	15 (4.6)	0.90
Upper intraabdominal	3 (3.7)	33 (10.2)	0.06
Intracranial	2 (2.5)	17 (5.2)	0.30
Maxillo-facial	2 (2.5)	15 (4.6)	0.40
Intrathoracic	1 (1.2)	9 (2.8)	0.43
Anesthetic factors			
Premedication	55 (67.9)	165 (50.9)	0.51
Agents used intraoperatively			
IV anesthetics	68 (84.0)	304 (93.8)	0.00
Benzodiazepine	37 (45.7)	121 (37.6)	0.17
Depo-neuromuscular blockade	21 (25.9)	125 (38.6)	0.03
Nondepo-neuromuscular blockade	75 (92.6)	272 (84.0)	0.04
Nitrous oxide	57 (70.4)	285 (88.0)	0.00
Inhalation anesthetics	76 (93.8)	303 (93.5)	0.92
Opioids	79 (97.5)	303 (93.5)	0.15
Local anesthetics	7 (8.6)	32 (9.9)	0.71

Values are numbers (percentages)

Results

Among 20 hospitals in Thailand from March 2003 to February 2004, intra-operative recall of awareness was reported in 81 cases. The authors matched these by age, gender, and level of hospital to 324 controls. Characteristics of cases and matched controls are shown in Table 1.

Table 2 shows the different risk factors in cases and their controls. Variables found to be significant on univariate analysis (p-value < 0.10) were site of surgery (cardiac, cesarean delivery, and upper intra-abdominal surgery) and agents used intra-operatively (IV anesthetics, depolarizing neuromuscular blockade, non-depolarizing neuromuscular blockade, and nitrous oxide).

Multivariate logistic regression analysis demonstrated a significantly increased risk of intra-operative recall of awareness in cesarean delivery (Odds ratio 6.48, 95% confidence interval 2.03 to 20.71), and in cardiac surgery (Odds ratio 10.37, 95% confidence interval 3.37 to 31.89) compared with all other sites of surgery. Decreased risk was associated with intra-operative use of nitrous oxide (Odds ratio 0.42, 95% confidence interval 0.20 to 0.88) (Table 3).

Discussion

The number of patients who have pre-operative anxiety over possibly waking up in the middle of surgery has increased dramatically over the last decade. For the patient, awareness or recall while under general anesthesia is a frightening experience that can lead to debilitating emotional injury and even post-traumatic stress disorders. The history of awareness during anesthesia is as old as the specialty of anesthesiology itself. During the first successful administration of ether, William Morton's patient reported being aware during the surgical procedure, but without pain. Performing surgery with little or no pain was

Table 3. Risk factors for awareness (multivariate analysis)

	ORs	95% CIs		p-value
Surgical factors				
Site of surgery				
Cardiac	10.36	3.37	31.89	<0.001
Cesarean delivery	6.48	2.03	20.71	<0.001
Upper intraabdominal	0.48	0.13	1.77	0.27
Anesthetic factors				
Agents used intraoperatively				
IV anesthetics	1.24	0.42	3.67	0.70
Depo-neuro-muscular blockade	0.56	0.28	1.14	0.11
Nondepo-neuro-muscular blockade	2.10	0.74	5.98	0.17
Nitrous oxide	0.42	0.20	0.88	0.02

such an advancement, that awareness of pain was not an issue. It was not until the advent and widespread use of neuromuscular blockades that awareness becomes a concern. After more than a century since the first anesthetic and almost 60 years since the introduction of neuromuscular blockers, the situation has changed very little and there is still no guaranteed method for determining anesthetic depth in a paralyzed patient.

In the authors' previous study, the Thai Anesthesia Incidents Study (THAI Study) revealed the incidence of intra-operative recall of awareness of 3.8 (95% confidence interval 2.6-5.0) per 10000 general anesthetics[31,32], which was comparable to other studies[2-8]. Another narrative revealed that awareness occurred at an incidence of 0.08% during 18 months period of the THAI Study[33]. The common characteristics were female gender, ASA physical status 1 and 2, cardiac, obstetric, and lower abdominal surgery. Therefore, this nested case-control study was designed to investigate the risk of intra-operative recall of awareness during a 12-months period with consistent data collection form appropriate for the analysis. The authors found a significantly increased risk of intra-operative recall of awareness in patients underwent cesarean delivery and cardiac surgery. This finding was consistent with previous reports[1,8]. The incidence of intra-operative recall of awareness was reported to be greater in some surgical procedures in which a smaller dose of anesthetics must be carefully titrated to decrease significant side effects such as cardiac, obstetric and major trauma cases[3-5,8,11,14-26]. Decreased risk was associated with intra-operative use of nitrous oxide in the present study. The possible explanation is nitrous oxide was shown to suppress memory and learning, though to a lesser extent than isoflurane[34]. Although anesthetic risk factors reported previously included the routine use of neuromuscular blockers, the increasing use of intravenous anesthesia is occurring, as opposed to inhalation[3,6-7,12,15,18,27-30]. The authors could not demonstrate any association of these factors with intra-operative recall of awareness in the present study. The possible explanation was that most of the patients underwent general anesthesia receiving inhale anesthetics.

In the present study, awareness was potentially a preventable adverse anesthetic outcome. The specific recommendations for the prevention of awareness included a consideration of intra-operative use of nitrous oxide[35], and inform of the possibility of intra-operative recall of awareness in patients at increased risk[36].

In summary, the incidence of intra-operative recall of awareness in the present study was associated with cesarean delivery, cardiac surgery, and intra-operative use of nitrous oxide. Cesarean delivery and cardiac surgery increased the risk of intra-operative awareness whereas the use of nitrous oxide decreased the risk of this adverse anesthetic event. Anesthesia personnel should identify patients at risk and make an effort to minimize the risks.

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ปัจจัยเสี่ยงของการเกิดภาวะรู้ตัวระหว่างผ่าตัดในโครงการศึกษาภาวะแทรกซ้อนทางวิสัญญีในประเทศไทย: การศึกษาแบบ case-control

มะลิ รุ่งเรืองวานิช, สมบูรณ์ เทียนทอง, สมรัตน์ จารุลักษณานันท์, วรินี เล็กประเสริฐ, อักษร พูลนิติพร, อังกาบ ปราการรัตน์

ภูมิหลัง: *เป็นการศึกษาปัจจัยเกี่ยวข้องกับการเกิดภาวะรู้ตัวระหว่างผ่าตัดในโครงการศึกษาภาวะแทรกซ้อนทางวิสัญญีในประเทศไทย*

วัตถุประสงค์: *เพื่อทำการศึกษาแบบทะเบียนโรคของการให้ยาระงับความรู้สึกในโรงพยาบาล 20 แห่งจากภูมิภาคต่าง ๆ ในประเทศไทย*

วัสดุและวิธีการ: *ข้อมูลผู้ป่วยที่มีภาวะรู้ตัวระหว่างผ่าตัดระหว่าง 1 มีนาคม พ.ศ. 2546 – 28 กุมภาพันธ์ พ.ศ. 2547 จะได้รับการทบทวนโดยวิสัญญีแพทย์ 3 คน โดยจับคู่กับผู้ป่วยในทะเบียนโรคที่ไม่เกิดภาวะรู้ตัวระหว่างผ่าตัดที่มีอายุ เพศ และได้รับการให้ยาระงับความรู้สึกในโรงพยาบาลระดับเดียวกัน วิเคราะห์แบบ univariate และ logistic regression โดยถือ $p < 0.1$ และ $p < 0.05$ มีนัยสำคัญทางสถิติตามลำดับ*

ผลการศึกษา: *จากการวิเคราะห์ผู้ป่วยที่มีภาวะรู้ตัวระหว่างผ่าตัด 81 ราย เทียบกับกลุ่มเปรียบเทียบ 324 ราย การวิเคราะห์แบบ univariate พบว่าการผ่าตัดหัวใจ การผ่าคลอด การผ่าตัดหน้าท้องส่วนบน การได้รับยาระงับความรู้สึกชนิดฉีดเข้าหลอดเลือดดำ ยาหย่อนกล้ามแบบ depolarizer และแบบ nondepolarizer และ nitrous oxide มีความเกี่ยวข้องกับการเกิดภาวะรู้ตัวระหว่างผ่าตัด ($p < 0.1$) ปัจจัยเสี่ยงโดย multivariable logistic regression ได้แก่ การผ่าคลอด $p < 0.001$, OR 6.48 (95% CI 2.03, 20.71); การผ่าตัดหัวใจ $p < 0.001$, OR 10.37 (95% CI 3.37, 31.89) ในขณะที่การใช้ nitrous oxide จะลดโอกาสเกิดภาวะรู้ตัวระหว่างผ่าตัด $p = 0.02$, OR 0.42 (95% CI 0.20, 0.88)*

สรุป: *ในโครงการ THAI Study ปัจจัยเสี่ยงต่อการเกิดภาวะรู้ตัวระหว่างผ่าตัด ได้แก่ การผ่าคลอด การผ่าตัดหัวใจ ในขณะที่ nitrous oxide จะลดโอกาสเสี่ยง*