

The Thai Anesthesia Incidents Study (THAI Study) of Morbidity after Spinal Anesthesia: A Multi-centered Registry of 40,271 Anesthetics

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Background: The present study was part of the Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes.

Objective: Study complications after spinal anesthesia.

Material and Method: During the 12 month period (March 1, 2003 – February 28, 2004), a prospective multi-centered descriptive study was conducted in 20 hospitals comprised of seven university, five tertiary, four general and four district hospitals across Thailand. Anesthesia personnel filled up patient-related, surgical-related, and anesthesia-related variables and adverse outcomes of all consecutive patients receiving anesthesia on a structured data entry form. The data were collected during pre-anesthetic, intra-operative, and 24 hr post operative period. Adverse event specific forms were used to record when these incidents occurred. Data were reviewed by three independent reviewers and analyzed to identify contributing factors by consensus.

Results: This was registry of 40,271 spinal anesthetics from 172,697 anesthetics. The incidence of total spinal anesthesia, neurological complications, suspected myocardial ischemia, or infarction and oxygen desaturation per 10000 spinal anesthetics were 3.48 (95% CI 1.66-5.30), 1.49 (95% CI 0.30-2.68), 2.73 (95% CI 1.12-4.35), 0.99 (95% CI 0.39-2.56), and 6.46 (95% CI 3.98-8.94) respectively. This was not different to the incidence in other countries. Risk factors of oxygen desaturation were shorter in height [OR 0.95 (95% CI 0.92-0.97); $p < 0.001$], higher ASA physical status [OR 3.37 (95% CI 1.98-5.72); $p < 0.001$], and use of propofol [OR 5.22 (95% CI 1.78-15.35); $p = 0.003$]. Other complications such as seizure, anaphylactic or anaphylactoid reaction, drug error, and pulmonary aspiration were scarce. There was no case of mismatched blood transfusion in the present study.

Conclusion: Incidence of total spinal block, neurological complication, and suspected myocardial ischemia or infarction was uncommon. Risk factors of oxygen destruction were shorter in height, higher ASA physical status, and use of propofol. Some events were considered avoidable and preventable.

Keywords: Spinal anesthesia, Complication, Total spinal block, Nerve injury, Desaturation

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Because it is rare for serious cardiac and neurological complications to occur in association with regional anesthesia, published information regarding critical serious events are found primarily as retrospective studies or case reports. Few prospective surveys assessing large numbers of patients have been published^(1,2).

The Royal College of Anesthesiologists of Thailand hosted the Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes for study of incidences and risk factors of anesthesia related complications^(3,4). The aims of the present study, as part of the THAI Study, were to investigate the adverse events after spinal anesthesia and identify risk factors. Spinal anesthesia is the most common regional anesthetic technique performed in Thailand.

Material and Method

The Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes was a prospective multi-centered registry of consecutive anesthetic performed in 20 hospitals (seven university hospitals: Chiang Mai University, Chulalongkorn University, Siriraj Hospital and Ramathibodi Hospital, Mahidol University, Pramonkutrakul Medical College, Prince of Songkhla University), five tertiary hospitals (Buddhachinaraj Hospital, Ratchaburi Hospital, Nakorn Sri Thammarat, Khon Kaen Hospital and Neurology Institution), 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) from all regions of 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 anesthesiologist or nurse anesthetist completed a preplanned structured data entry form 1 (form 1) that 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. Since the authors were relying on compliance by all anesthesia personnel, workshop 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, was confined to patients receiving spinal anesthesia only. When regional and general anesthesia were combined, only general anesthesia was considered according to the anesthetic technique. For the recording of patient related variables, the attending anesthesia personnel were requested to fill in pre-operative medical conditions, the American Society of Anesthesiologists (ASA) physical status scores, and demographic characteristics of the patients. With regard to the surgical procedure, the operations were recorded by converting the written operative procedure into groups of sites of operations. The factors recorded relating to anesthesia including monitors, main anesthetic technique, additional anesthetic technique employed, airway equipment, status of performer of anesthesia, and drug utilized.

For in-patients, with 24-hr after the surgical procedure, the anesthesia personnel or research nurses visited the patient to record 24 hr anesthesia related adverse outcomes for out-patients, however, follow up of all patients was not possible. The adverse outcomes of interest included total spinal block, nerve injuries, transfusion mismatch, seizure or convulsion, suspected myocardial ischemia or infarction, desaturation ($SpO_2 \leq 85$ or ≤ 90 for more than 3 min), anaphylaxis/anaphylactoid reaction, drug error and pulmonary aspiration.

Whenever the adverse events of interest occurred, the details of events were recorded in event specific data entry form (form 2). For purposes of analysis, timing of adverse events was divided into three periods: intra-operative period, in the recovery room, or post operative period (within 24 hour after the operation).

All forms were reviewed by a research nurse or site manager for completeness. Corrections were then made by each centre including the verification of the major event recorded. Incompleteness after this step was considered as missing.

Data collection and analysis

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

Results

During the period from 1st March 2003 to 28th February 2004, 172,697 anesthetics had been carried out in 20 hospitals. Of these, 40,271 (23.3%) spinal anesthesia were performed for 22,851 (56.7%) male and 17,382 (43.2%) female and 38 cases of (0.1%) missing gender data. According to the American Society of Anesthesiologists' definition, these patients were classified as ASA physical status 1, 2, 3 and 4 in 23,653 (58.7%), 14,603 (36.3%), 3,752 (4.7%) and 1,486 (0.2%) respectively. The procedures were conducted as an emergency setting in 13,807 (34.3%) respectively. Details of site of surgery or types of operation were as follows:- extremity 13,902 cases (34.5%), Cesarean section 11,296 cases (28.0%), lower abdominal surgery 5,258 cases (13.1%), and perineal-anal surgery 4,073 cases (10.1%). Spinal anesthesia was conducted in university hospitals (56.4%), regional hospitals (32.9%), provincial or general hospitals (9.8%), and district hospitals (0.9%) respectively. The performers of spinal anesthesia were as follows: anesthesiologists (48.0%), surgeon (5.2%), anesthesia residents (31.9%), rotating residents (8.4%), and medical students under supervision of anesthesiologists (6.5%). There were 19,366 patients (48.1%) who had abnormal pre-anesthetic abnormality namely 4,906 cases (12.2%) of hypertension, 3,426 cases (8.5%) of diabetes mellitus, 2,323 cases (5.8%) of anemia, 1,078 cases (2.8%) of renal insufficiency, etc. Most of the patients (30,996 or 77.7%) received no premedication, while 5,966 patients (14.8%) received midazolam, 627 patients (1.6%) received diazepam, and 1,855 patients (4.6%) received ranitidine respectively. Adverse events according to time periods are demonstrated in Table 1.

Total spinal anesthesia

There were six cases of total spinal anesthesia with the incidence of 1.49 (95% confidence interval 0.30-2.68) per 10000. Five out of six (83.3%), were parturients undergoing cesarean section. All of them were female and classified as ASA physical status 1 or 2 while 50% of patients were operated on under emergency conditions. Among cesarean section cases, two cases developed total spinal anesthesia despite left lateral uterine displacement, one case occurred after barbotage of local anesthetic and another case of double injection of 0.5% isobaric bupivacaine because of inadequate anesthesia. There was only one geriatric case of total spinal anesthesia after intrathecal administration of 1.5 cc of 5% lidocaine for surgery of extremity. Summary of cases is shown in Table 2.

Neurological complication

Neurological complications presented within 24 hour of surgery in 11 patients. Permanent neurological sequelae occurred in two cases (18.18%). The first patient undergoing open reduction and internal fixation of femur developed motor weakness because of pre-anesthetic undetection of spinal cord tumor at Lumbar spine level 3 to 5. The second patient had undetected metastasis to the lumbar spine, received spinal block for total hip replacement, and later on was scheduled for nerve root decompression. One case had no data about recovery. Nine patients had transient sequelae associated with lumbosacral nerve (8 cases; 72.73%) and common peroneal nerve (1 cases; 9.09%). Summary of patients with neurological sequelae is shown in Table 3.

Table 1. Anesthesia related adverse events after spinal anesthesia

	Period of events			Total patients	Incidence:10000 (95% CI)
	Intra-operative	Recovery	24 hr post-operative		
Total spinal anesthesia	6	0	0	6	1.49 (0.30-2.68)
Convulsion (seizure)	3	1	0	4	0.99 (0.39-2.56)
Nerve injury	0	0	11	11	2.73 (1.12-4.35)
Suspected myocardial infarction or ischemia	4	0	0	4	0.99 (0.39-2.56)
Desaturation	13	13	2	26	6.46 (3.98-8.94)
Ansphylaxis or anaphylactoid reaction	2	0	2	2	0.50 (0.14-1.81)
Drug error	3	0	1	4	0.99 (0.39-2.56)
Pulmonary aspiration	0	1	0	1	0.25 (0.04-1.41)

* Value are not mutually exclusive

Table 2. Characteristics of patients with total spinal anesthesia

Patient number	Gender	Age (yr)	ASA PS	Operation or site of operation	Anesthetics	Performer	Analgesic level	Clinical setting	Outcome
1	F	30	IE	Cesarean section [+hysterectomy]	0.5% heavy bupivacaine (1.8 mL)	Surgeon	T4	4 min after delivery, Intubation, no chest compression, epinephrine Uterine atony	Recover Unplanned ICU admission extubation (day 2)
2	F	22	I	Cesarean section [+hysterectomy]	0.5% isobaric bupivacaine (2 mL) (twice due to inadequate analgesia) with left uterine displacement	Surgeon	-	Sudden, seizure, cardiovascular collapse, Intubation, Atropine, Adrenaline Chest compression Uterine atomy, DIC	CPR for 27 min Unplanned ICU admission Death within 24 hr
3	F	38	2E	Cesarean section	0.5% heavy bupivacaine (2.2 mL) left uterine displacement	Surgeon	-	Sudden, seizure Intubation Chest compression Adrenaline Defibrillation	Death within 24 hr
4	F	27	IE	Cesarean section	0.5% heavy bupivacaine (2.2 mL)	Resident	T1	Apnea, seizure Unconscious Intubation Assist ventilation	Recover Gain consciousness Extubation
5	F	30	I	Cesarean section [+tubal resection]	0.5% heavy bupivacaine + morphine 0.2 mg (2.4 mL)	Anesthesiologist	T3	Vigorous delivery 2 min after delivery Apnea, Unconscious 100% O ₂ mask ventilation	Recover Gain consciousness
6	F	72	2	Extremities	5% xylocaine (1.5 mL)	Anesthesiologist	-	intubation general anesthesia	Recover Gain conscious Extubation after surgery

(Abbreviation: F = female, E = emergency)

Table 3. Characteristics of patients with neurological complication after spinal anesthesia

Patient Number	Gender	ASA	PS	Age (yr)	Operation or site of procedure	Duration of operation (min)	Position	Nerve	Remarks
1	F	2		64	Vaginal hysterectomy +Antero-posterior repair	120	Lithotomy	Common peroneal	Recover
2	M	1		35	Extremities : femur	105	Supine	Lumbosacral	Spinal cord tumor L _{3,4,5}
3	M	1		58	Total hip replacement	105	Supine	Lumbosacral	Pain during intrathecal injection Metastasis at lumbar spine L _{2,3} surgical decompression
4	F	2		61	Total knee replacement	200	Supine	Lumbosacral	Recover at day 3
5	F	1		25	Cesarean section	60	Supine	Lumbosacral	Recover at day 3
6	M	IE		16	Extremities : femur	135	Supine	Lumbosacral	Recover at day 3
7	F	1		45	Groin nodes dissection	140	Lithotomy	Femoral	Recover at day 14 (surgical cause)
8	F	2		50	Extremities: biopsy mass below sciatic nerve	120	Supine	Sciatic	No data about recovery (surgical cause)
9	F	IE		30	Cesarean section	40	Supine	Lumbosacral	Recover at day 3
10	M	2		60	Excision of paraffinoma at penis	60	Supine	Lumbosacral	Recover at day 2
11	M	2		72	Extremities	50	Supine	Lumbosacral	Recover at day 6

Abbreviation: F = female, M = male, M = male, E = emergency

Table 4. Characteristics of patients with suspected myocardial ischemia or infarction after spinal anesthesia

Patient No.	Gender	Age	ASA PS	Surgery or site of operation	Patient condition	Anesthesia	Treatment	Outcome
1	F	73	2	Superficial (Debridement)	HT Arrhythmia	Proload fluid 200 ml No leg wrapping 0.5% bupivacaine (3.6 ml) Hypotension BP 70/40 no symptom	Ephedrine Atropine Nitroglycerine Lidocaine Dopamine	- ST depression, PVC - recover in OR after treatment
2	M	43	3E	Extremity (Debridement)	HT DM Renal insufficiency Smoking	0.5% bupivacaine (3 ml) ST depression, hypotension No symptom	Ephedrine Nitroglycerine Dopamine	- unplanned ICU admission - resolve
3	M	67	2	Superficial (Debridement)	HT IHD (post PTCA) Smoking	0.5% bupivacaine (1.8 ml) Chest pain, hypotension Tachycardia 120-150/min	Ephedrine Colloid Nitroglycerine Dopamine Esmolol	- unplanned ICU admission - resolve
4	M	49	3	Cystoscopy	HT IHD	0.5% bupivacaine (2.5 ml) chest pain hypotension bradycardia	Atropine Nitroglycerine Dopamine Morphine	- unplanned ICU admission - resolve

Abbreviation: M = male, F = female, HT = hypertension, DM = diabetes melitus, IHD = ischemic heart disease

Seizure

All four reported seizures were associated with oxygen desaturation (100%), and three cases (75%) occurred with hypotension. Two cases of seizure (50%) were consequences of high spinal block while another occurred intra-operatively because of pulmonary embolism and the last occurred in the recovery room as a consequence of pulmonary aspiration. Most cases (75%) improved after supportive treatment of oxygen desaturation and hypotension except one fatal outcome due to pulmonary embolism.

Suspected myocardial ischemia or infarction

Four cases of suspected myocardial ischemia or infarction were reported with an estimated incidence of 0.99 (95% confidence interval 0.39-2.56) per 10000. Three cases (75%) were male patients. Summary of cases characteristics is shown in Table 4. All cases were admitted to intensive care unit and recovered after treatment.

Oxygen desaturation

Oxygen desaturation was reported in 26 cases with an incidence of 6.46 (95% confidence interval 3.98-8.94) per 10000. The period of oxygen desaturation were intra-operative for 13 cases or 3.23 (95% con-

fidence interval 1.47-4.94) per 10000; recovery room period for 13 cases or 3.23 (95% confidence interval 1.47-4.98) per 10000 and 24 hr postoperative period for two cases or 0.5 (95% confidence interval 0.14-1.81) per 10000 respectively. The characteristics of patients with and without oxygen desaturation (univariate analysis) are presented in Table 5. Factors associated with a higher risk of oxygen desaturation were short height [OR 0.95 (95% CI 0.92-0.97), $p < 0.001$], higher ASA physical status [OR 3.37 (95% CI 1.98-5.72), $p < 0.001$] and propofol administration [OR 5.22 (95% CI 1.78-15.35), $p = 0.003$] respectively.

Anaphylaxis or anaphylactoid reaction

There were two cases of intra-operative anaphylaxis or anaphylactoid reaction and two cases in 24-hr., post operative period after conduction of spinal anesthesia. The etiologic agents of intra-operative incidents were cefazolin and polygeline (Haemacel), which produced severe hypotension and skin reaction (1 case of urticaria and 1 case skin flushing and rash respectively). Both patients responded well to vasopressor, antihistamine, and dexamethasone. The third case was a parturient undergoing cesarean section, which developed angioedema after intramuscular injection of diclofenac sodium during 24 hr postopera-

Table 5. Characteristics of patients receiving spinal anesthesia with and without oxygen desaturation (univariate analysis)

	Total	Desaturation	No desaturation	p-value
Gender	40233			0.061
Female	22851	20 (0.1%)	22831 (99.9%)	
Male	17382	6 (0.0%)	17376 (100%)	
Age (yr)		47.8 (25.6)	42.1 (18.7)	0.270
Weight (kg)		57.3 (13.3)	61.4 (12.2)	0.086
Height (cm)		154.4 (6.6)	159.8 (8.1)	0.001
Body mass index (BMI)	39636			0.449
BMI < 35		23 (0.1%)	38641 (99.9%)	
BMI ≥ 35		1 (0.1%)	971 (99.9%)	
ASA PS	40208			<0.001
1	23654	6 (0.0%)	23648 (100.0%)	
2	14603	13 (0.1%)	14590 (99.9%)	
3	1885	7 (0.4%)	1878 (99.6%)	
4	66	0 (0.0%)	66 (100%)	
Emergency	13807	8 (0.1%)	13799 (99.9%)	0.864
Medication	40271			
Midazolam	5595	7 (0.1%)	5588 (99.9%)	0.080
Diazepam	926	2 (0.2%)	924 (99.8%)	0.120
Propofol	1489	4 (0.3%)	1485 (99.7%)	0.015
Fentanyl	2749	4 (0.1%)	2745 (99.9%)	0.098

tive period without cardiovascular adverse event. She was treated with antihistamine and dexamethasone and angioedema disappeared on the same day. The fourth case developed, skin rash, swelling, and bronchospasm after oral administration of ibuprofen. This patient recovered quickly after treatment by antihistamine and dexamethasone.

Drug error

Three cases of drug error occurred, two cases of intra-operative and one case of post operative drug error. The first case was syringe swap, succinyl choline instead of ephedrine, stopped intravenous injection after 0.5 mL intravenous administration without harm (near-miss occurrence). The second case was also syringe swap, morphine instead of metoclopramide for nausea. This patient had no adverse event. The third case was a patient who received 4 mg morphine IV despite having an intrathecal morphine injection for post operative analgesia. This patient was closely observed and no respiratory depression occurred.

Pulmonary aspiration

There was a case of pulmonary aspiration. The patient was a 75-yr. old female with pre-operative diagnosis of dementia with brain atrophy who developed oxygen desaturation in the recovery room. Prompt treatment was suction fluid from oral cavity, intubation, and suction through an endotracheal tube. The patient was transferred to the intensive care unit. This case was resolved in 3 days after admission to the intensive care unit with support treatment.

There was no transfusion mismatch reported during the 12 month period of the present study.

Discussion

The present study was part of the Thai Anesthesia Incidents Study (THAI Study) to investigate adverse events after spinal anesthesia during a 12-month period. The authors were able to include 40,271 consecutive cases (23.3%) of spinal anesthesia out of 172,697 anesthetics. The authors' approach was successful in obtaining prospective data for investigation. There were limitations of the present study: 1) More than half of the data belonged to university hospitals that did not represent the true proportion of types of hospitals in Thailand but these data provided accepted quality of details. 2) There were missing data despite correction and completeness process by site managers. 3) There were no specialists or consultants in some participating hospitals who could provide more infor-

mation or accurate diagnosis. The study process had an internal audit to recruit each site which could collect more than 90% of total anesthetics to be the site for multi-centered studies. External audits by external evaluators from institutes of other specialties were also conducted in a few university hospitals. The principle investigators or reviewers of the present study communicated and asked for more details from site managers before considering the incompleteness and the amount of missing data.

There were more males (56.7%) than females (43.2%) patients despite 11,296 (28.0%) cases of cesarean section. Therefore, a higher proportion of male patients were operated under spinal anesthesia especially in perineal-anal, extremities, and lower abdominal surgery. Those were the most common surgeries performed. The percentages of patients with ASA physical status 1 was high compared to the proportion of patients receiving all choices of anesthesia. A possible explanation was that a patient with ASA physical status 1 was considered a good candidate for spinal anesthesia. Moreover, the proportion of emergency cases (34.7%) in the present study was higher than the proportion of emergency patients receiving all choices of anesthesia in a previous study⁽³⁾. The majority of performers of spinal anesthesia were MD anesthesiologists and other types of trainees under supervision. There were 2,110 patients (5.2%) who were anesthetized by surgeons especially in provincial hospitals (general hospitals) with few MD anesthesiologists or no MD anesthesiologists.

Total spinal block

All cases of total spinal block in the present study were female. The explanation is five out of six cases were cesarean section patients. Therefore, cesarean section parturient should be considered as high risk of total spinal block. The onset of total spinal block varied from immediate onset after conduction of anesthesia to 4 min after childbirth. Vigorous delivery of a baby was reported in one case. In the delayed onset pattern, some patients were perfectly conscious at first and presented a gradual increase of the difficulty in talking and breathing. Subsequently, they showed a complete paralysis with loss of consciousness, respiratory arrest, bilateral and symmetrical midriasis, as well as total areflexia. Management of total spinal block was symptomatic treatment including airway management with or without endotracheal intubation, atropine, and vasopressor including adrenaline administration with or without chest compression.

When the local anesthetics wore off, block regression started when the respiratory movements become noticeable, eye opening and hand movements returned^(5,6). In the present study, two out of six (33.3%) total spinal block had fatal outcome; three out of six (50.0%) performers of spinal anesthesia were surgeons.

Neurological complication

Perioperative nerve injuries may be divided into two categories: those unrelated to regional anesthetic techniques and those that are a direct result of regional anesthetics. The two cases of permanent neurological sequelae after spinal anesthesia in the present study occurred as consequences of conduction of spinal anesthesia in patients with undetected tumors or malignancy at the lumbar spine level. Therefore, pre-anesthetic evaluation remains crucial for any anesthetic procedure. From these two cases, one patient complained of pain during intrathecal administration of local anesthetic, therefore pain during injection may be considered a warning sign. Two cases (18.2%) were considered surgical related neurological complication because of intra-operative surgical traction of nerve. Position (lithotomy) was considered a contributing factor in a case of transient neurological consequence of common peroneal nerve. Lumbosacral radiculopathy was common among transient neurological symptoms (TNS). Recent interest in neurotoxicity has arisen because of concerns over reports of cauda equina syndrome and TNS from spinal local anesthetics. Nearly all cases of spinal anesthesia during the study period received intrathecal administration of 0.5% bupivacaine. Recent retrospective, prospective, and closed claims studies report an incidence of post operative neurological injury in patients undergoing spinal anesthesia between 0 and 0.7%⁽⁷⁻¹⁰⁾. The incidence of neurological complication in the present study was comparable to previous studies. However, details of neurological complications were insufficient and there was no consultant specialist in some hospitals. This was a limitation of the present study. Risk factors contributing to neurological defects after regional anesthesia include neural ischemia, traumatic injury to the nerves during needle or catheter placement, infection, and choice of local anesthetic solution^(11,12). Moreover, post operative neurological injury as a result of pressure from improper patient positioning or from tightly applied casts or surgical dressing, as well as surgical trauma, is often attributed to the regional anesthetics⁽¹³⁾. Patient factors such as body habitus or a pre-existing neurological dysfunction may also contribute^(14,15).

Prevention of complications along with early diagnosis and treatment are important in the management of regional anesthetic risks.

Seizure

All cases of seizure associated with oxygen desaturation and three-fourths developed hypotension. The possible explanation of seizure might be cerebral hypoxia due to cerebral hypoperfusion⁽⁷⁾. Because of the small dose of bupivacaine intrathecally administered, the authors can exclude the possibility of systemic toxicity. The present study revealed a higher incidence of seizure while Auroy's survey showed no seizure in 40, 640 cases of spinal anesthesia⁽⁷⁾.

Suspected myocardial ischemia on infarction

In the present study, myocardial ischemia or infarction was suspected when new ST-segment change (elevation or depression) occurred with hypotension, which could not be explained by other causes, or elevation of cardiac enzymes or nitroglycerine was administered for coronary effect or definite diagnosis by autopsy, echocardiography or coronary angiography. Therefore, prevalence of suspected myocardial ischemia or infarction after spinal anesthesia of 0.99 (95% CI 0.39-2.56) per 10000 in the present study may be under-estimated. In a previous study the incidence of suspected myocardial ischemia or infarction after all types of anesthesia was 2.7: 10000⁽⁴⁾. Some patients in the present study might be the same individuals in our former study, which started at a different month. However, risk factors of suspected myocardial ischemia or infarction in the present study might be male gender (75%), ASA physical classification ≥ 2 (100%), underlying hypertension (100%), ischemic heart disease (50%), history of heavy smoking (50%), hypotension (100%), chest pain (50%) and change in EKG were primary clinical symptoms that were similar to a previous study⁽¹⁵⁾.

Oxygen desaturation

There were only 26 cases of oxygen desaturation. This might be under reported. Desaturation occurred in both genders and all age groups. Shorter height, higher ASA physical status, and use of propofol were risk factors with both univariate and multivariate analysis. However, body mass index > 35 did not show statistical significance with occurrence of oxygen desaturation. According to the operative definition; oxygen saturation $< 90\%$ lasting for at least 3 min or oxygen saturation 85% were considered as desatura-

tion. In the present study, the incidence of oxygen desaturation after spinal anesthesia of 6.46 per 10000 was lower than incidence of oxygen desaturation occurred with any choice of anesthesia of 31.9:10000⁽⁴⁾. The possible explanation is most patients receiving spinal anesthesia were conscious and received less airway manipulation. Therefore, prevention of oxygen desaturation in high risk patients such as shorter height patients and higher level of ASA physical status patients and avoiding propofol or careful management of patients with alteration of consciousness should be a strategic method to minimize there adverse events.

Other complications such as anaphylaxis or anaphylactoid reaction, drug error, and pulmonary aspiration occurred at low rate. These might be underestimated because of being under reported.

Conclusion

The Thai Anesthesia Incidents Study (THAI Study) of anesthetic adverse outcomes after spinal anesthesia in 40,271 consecutive cases revealed incidence of serious adverse events such as in total spinal block, neurological complication and suspected myocardial ischemia or infarction were uncommon and not different from incidences in other western countries. Risk factors of oxygen desaturation were short height and higher ASA physical status. Other complications such as anaphylactic or anaphylactoid reaction, drug error and pulmonary aspiration were scarce but may lead to mortality or morbidity. Some complications were considered avoidable and preventable.

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โครงการเฝ้าระวังภาวะแทรกซ้อนจากการฉีดยาชาเข่าน้ำไขสันหลังในประเทศไทย: การศึกษา สหสถาบันแบบทะเบียนโรค 40,271 ราย

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ภูมิหลัง: การศึกษานี้เป็นส่วนหนึ่งของโครงการเฝ้าระวังภาวะแทรกซ้อนทางวิสัญญีในประเทศไทย

วัตถุประสงค์: เพื่อศึกษาอุบัติการณ์และปัจจัยเกี่ยวข้องกับภาวะแทรกซ้อน เนื่องจากการฉีดยาชาเข่าน้ำไขสันหลัง **วัสดุและวิธีการ:** ทำการศึกษาแบบพรรณนาชนิดไปข้างหน้าในการเก็บข้อมูลผู้ป่วยที่ได้ยาระงับความรู้สึกทุกราย ในโรงพยาบาล 20 แห่งในภูมิภาคต่าง ๆ ของประเทศไทย (โรงพยาบาลมหาวิทยาลัย 7 แห่ง, โรงพยาบาลตติยภูมิ 5 แห่ง, โรงพยาบาลทั่วไป 4 แห่ง และโรงพยาบาลชุมชน 4 แห่ง) ช่วงระยะเวลา 1 ปี (ตั้งแต่ 1 มีนาคม พ.ศ. 2546 – 28 กุมภาพันธ์ พ.ศ. 2547) โดยบุคลากรวิสัญญีเป็นผู้กรอกข้อมูลก่อน ระหว่าง จนถึงเวลา 24 ชั่วโมงหลังการผ่าตัดในแบบฟอร์มข้อมูลเชิงโครงสร้าง ซึ่งมีข้อมูลเกี่ยวกับตัวผู้ป่วยด้านศัลยกรรม และข้อมูลด้านวิสัญญี เมื่อเกิดภาวะแทรกซ้อนจะทำการกรอกข้อมูลในแบบฟอร์มเฉพาะเหตุการณ์ วิสัญญีแพทย์อาวุโส 3 ท่านเป็นผู้ประเมินข้อมูลเพื่อวิเคราะห์หาปัจจัยเกี่ยวข้อง โดยความเห็นแบบฉันทานุมัติ

ผลการศึกษา: จากการศึกษาแบบทะเบียนโรคในผู้ป่วยที่ได้รับการฉีดยาชาเข่าน้ำไขสันหลัง 40,271 รายของจำนวนการให้ยาระงับความรู้สึกทั้งหมด 172,697 พบอุบัติการณ์การเกิดภาวะ *total spinal anesthesia*, การบาดเจ็บของเส้นประสาท, ภาวะสงสัยกล้ามเนื้อหัวใจตายหรือขาดเลือดและภาวะออกซิเจนต่ำต่อ 10000 รายเท่ากับ 3.48 (95% CI 1.66-5.30), 1.49 (95% CI 0.30-2.68), 2.73 (95% CI 1.12-4.35), 0.99 (95% CI 0.39-2.56) และ 6.46 (95% CI 3.98-8.94) ตามลำดับ ซึ่งไม่แตกต่างจากข้อมูลในต่างประเทศ ปัจจัยเกี่ยวข้องกับภาวะความอิมมิตัวของออกซิเจนต่ำ ได้แก่ ส่วนสูงที่ต่ำกว่า, ASA physical status ที่สูงขึ้น และการได้รับยาพรีฟิวล ภาวะแทรกซ้อนอื่น ๆ ได้แก่ การชัก, ภาวะอนาไฟแลกซีส หรืออนาไฟแลกตอยด์, การไช่ยาผิดและการสำลักเข้าปอดเกิดในอัตราต่ำ โดยไม่พบการให้เลือดผิดในการศึกษานี้

สรุป: อุบัติการณ์เกิดภาวะแทรกซ้อนหลังการฉีดยาชาเข่าน้ำไขสันหลัง ได้แก่ ภาวะ *total spinal*, ภาวะแทรกซ้อนของระบบประสาท และภาวะกล้ามเนื้อหัวใจตายหรือขาดเลือดพบไม่บ่อย ปัจจัยเกี่ยวข้องกับภาวะระดับความอิมมิตัวของออกซิเจนในเลือดต่ำ ได้แก่ ส่วนสูงต่ำ [OR 0.95 (95% CI 0.92-0.97); $p < 0.001$] ASA physical status สูง [OR 3.37 (95% CI 1.98-5.72); $p < 0.001$] และการได้รับยาพรีฟิวล [OR 5.22 (95% CI 1.78-15.35); $p = 0.003$] ซึ่งภาวะแทรกซ้อนที่เกิดขึ้นบางกรณีสามารถหลีกเลี่ยงและป้องกันได้