

The Thai Anesthesia Incidents Study (THAI Study) of Perioperative Convulsion

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Objectives : To identify the incidence of perioperative convulsion within 24 hours, outcome, predisposing risk factors, contributing factors related to anesthesia and corrective strategies.

Material and Method : The prospective cohort study enrolled all anesthetics from twenty eligible hospitals in Thailand between March 1, 2003, and February 28, 2004. Postoperative convulsion incidents were extracted from the Thai Anesthesia Incidents Study (THAI Study) database in terms of demographic data, details of events, outcome, contributing factors related to anesthesia and corrective strategies.

Results : The incidence of perioperative convulsion was 3.1 per 10,000 from all 172,592 anesthetics. Most patients (73.59%) recovered in 24 hours. The majority of risk factors were related to surgery (67.92%) and patient factors (54.72%) while anesthesia was the minor factor (30.19%). The contributing factors related to anesthesia were medication error (route, type, time) 43.75% and human error (inadequate care, inadequate knowledge, inadequate communication) 43.75%. The important corrective strategies included improved supervision and clinical practice guideline.

Conclusion : The incidence of postoperative convulsion was 3.1 per 10000. Anesthesia was the minor contributing factor. The most important risk factors included medication error and human error.

Keywords: Postoperative convulsion, Anesthetic related, Incidence, Contributing factors

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The risk of complications in conjunction with surgery and anesthesia has been studied and published extensively⁽¹⁻⁶⁾. To determine the prevalence of those complications, large sample sizes are required, as such complications are rare events⁽²⁾. Taking into account of this, a prospective survey of complications associated with anesthesia was conducted in Thailand between March 1, 2003 to February 28, 2004 by the Collaboration of Research Center Network and The Royal College of the Anesthesiologists of Thailand as the Thai Anesthesia Incidents Study (THAI Study) of anesthetic outcomes. The participants of multicenter reported 172,592 cases from 20 hospitals. The incidence

of severe, anesthetic related complications was rare, substantially less than 0.2%. Focusing on neurology, neurological complications were summarized into stroke, awareness, convulsion and peripheral nerve injury. These sequelae were found to be 0.16% and present within 24 hours of surgery.

Although these adverse events occurred infrequently they did not only harmfully affect the patients, the relatives and socioeconomic but also reflected the quality of medical personnel, equipments, organizations and strategy of care.

The reported incidences of post operative convulsion vary between 2.2 in 10000 patients⁽⁵⁾ to 0.01% in normal population⁽⁷⁾ and 0.005 — 12.6% in high risk group such as post carotid endarterectomy⁽⁸⁾, post craniotomy⁽⁹⁾ and post open heart surgery⁽¹⁰⁾.

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Based upon the surveillance, identifications for the differences in patient, surgery and mainly on anesthesia may facilitate the risk factors, contributing factors and direct to the preventability and corrective strategy. A descriptive prospective study of reported post operative convulsion was undertaken and aimed to measure the overall rate of convulsion which occurred postoperatively and to identify any predisposing risk factors associated with convulsion including any contributing factors attributable to anesthesia.

Material and Method

In 2004 the post operative Neurological complications Committee was established within the institution of the Collaborative Research Center Network and the Royal College of Anesthesiologists of Thailand in order to prepare and organize this present study. The committee consisted of 5 anesthesiologists from different sites who attached precisely to neuroanesthesia. The protocol was a part of THAI Study which was approved by the Institutional Board Review. Confidentiality and the privacy of the participating anesthesiologists were secured legally.

The prospectively defined cohort from which the case arose comprised all patients undergoing either general, regional, nerve block, monitored anesthetic care or combined anesthesia from March 1, 2003 to February 28, 2004 in affiliated 20 hospitals, 4 regions to minimize the geographic and seasonal variation. The selection of institutions included in this study was performed, determining by the appropriateness of local site, the availability of anesthesiologists and the controllable capability of quality assessment.

The eligible hospitals were recruited and classified into 4 categories according to the annual volume of surgical and obstetrical beds, the operating theatre, the subspecialty and the academic situation of the hospital. The anesthesiologists were asked to approach a member correspondent to act as an intermediary between the local staff and the investigated committee. All patients were enrolled and recorded the demographic data, site of the operation, procedure, preanesthetic condition, anesthetic techniques, intraoperative monitoring, agents and anesthetic complications. Whenever the postoperative convulsion were detected, the correspondent had to be informed in order to complete the occurrence information ; identify main related factors, contributing factors, type of operations, patient conditions and the degree of anesthetic relation and evaluate the adequacy of management, the preventability and suggested corrective strategy.

Perioperative convulsion was defined as a violent involuntary contraction or series of contractions of the voluntary muscles or a sudden, violent, uncontrollable contraction of a group of muscles. In addition, whether the decision of the correspondent was diagnosed or undetermined, the whole collected document had to be included and critically evaluated by the committee. Each incident was known by a unique identification number to which only the correspondent and the project management had access.

The preliminary data was analyzed, reviewed and audited by 2 independent Postoperative Neurological Complications Committee members. In the event of a disagreement between the opinions, a separate consensus meeting was held with an expanded committee that was required to arrive at a final conclusion. If necessary, additional information was requested from the local correspondent. The analysis was presented descriptively in number and percent.

Results

There were 53 perioperative convulsion reported (3.1 per 10000). Patient characteristics, number of occurrences, place and period of occurrences including outcome are shown in table 1. Majority of events (66.04%) occurred as first episode , 56.61% in University hospital and 56.61% in postoperative period .

Thirty cases (56.61%) of these complications were treated properly which included emergency cardiovascular support, respiratory care and neurological management. Twenty one of the 53 (39.63%) cases were defined unpreventable while 16 (28.57%) cases were partially preventable and 13 (24.53%) cases were preventable events.

Evaluation of the data records of the fifty three patients who developed postoperative convulsion, indicated that anesthesia contributed to the complications in 16 (30.19%) patients. Thirty six patients (67.92%) were related to surgery and the remaining 29 (54.72%) patients were risky pertained to their preexisting condition for example increased intracranial pressure, valvular heart disease, metabolic disturbance, endocrinopathy, unstable hemodynamic, etc. Among the fifty three patients, there were 24 (45.28%) cases identified as the combinations of at least 2 from the 3 main related factors. The degree of anesthetic relation and the definition mentioned above are shown in table 2. Majority of events related to anesthesia were contributed to medication error and human error (table 3). Suggested corrective strategies were illustrated in table 4.

Table 1. Patient characteristics and the occurrences of perioperative convulsion

Data	Number (%)
Sex	
Male	31 (58.49)
Female	22 (41.51)
Age	
< 12 years	11 (20.76)
12 - 65 years	33 (62.27)
> 65 years	9 (16.99)
Occurrence	
First episode	35 (66.04)
Have had convulsion history but no symptoms within 6 months	10 (18.87)
Develop postanesthesia and have had symptoms within 6 months	8 (15.10)
Outcome	
Recover within 24 hours	39 (73.59)
Not recover within 24 hours	12 (22.65)
Inadequate data	2 (3.78)
Place of occurrence	
University hospital	30 (56.61)
Tertiary care hospital	20 (37.74)
Secondary care hospital	2 (3.78)
Primary care hospital	1 (1.89)
Period of occurrence	
Intraoperative period	10 (18.87)
Recovery period	13 (24.53)
Postoperative within 24 hours	30 (56.61)

Table 2. The degree of anesthetic relation to the occurrence

Main related factors	Number (%)
1. Cases in which it was reasonably clear that convulsion was caused by the anesthetics	7 (13.21)
2. Similar cases to those in category 1 but in which there was some doubt	4 (7.55)
3. Convulsion cases in which was caused by both anesthetic and surgery	5 (9.44)
4. Convulsion entirely referable to surgery	25 (47.17)
5. Inevitable incidence	4 (7.55)
6. Fortuitous incidence	3 (5.66)
7. Convulsion cases which could not be assessed despite considerable data	4 (7.55)
8. Inadequate data	1 (1.89)

Discussion

This report is a prospective study of perioperative convulsion associated with anesthesia. From our study, the incidence of perioperative convulsion was 3.1 per 10,000 from all 172,592 anesthetics.

Most patients (73.59%) recovered in 24 hours. Several advantages of prospective studies can be found over the retrospective surveys. In prospective study, detailed information are available about the circumstances, types of the occurrence and also the data regarding the preoperative status unlike the retrospec-

Table 3. The etiology and the outcome of perioperative convulsion

Cause	Out-come	Number (%)
Medication error		
1. Mistaken injection route		
- Accidental intravascular injection of local anesthetic during brachial plexus block	R	2 (12.5)
- Accidental intravascular injection of local anesthetic during epidural block	R	1 (6.25)
- Accidental intravascular injection of local anesthetic during caudal block	R	1 (6.25)
2. Mistaken injection type		
- Reaction from propofol injection	R	1 (6.25)
3. Mistaken injection time		
- Delay of anticonvulsant therapy	N	2 (12.5)
Human error		
1. Inadequate care		
- Brain anoxia from postoperative apnea after deep sedation	N	1 (6.25)
- Brain anoxia from severe hypovolemia	N	1 (6.25)
- Delay treatment of intraoperative hypotension resulted in decrease cerebral blood flow	R	3 (18.75)
2. Inadequate knowledge		
- Delay detection of pleural effusion resulted in brain anoxia	N	1 (6.25)
3. Inadequate communication		
- Underestimated end time leading to hypercarbia during emergence	R	1 (6.25)
Improper organization		
- Brain anoxia during fiberoptic intubation	N	1 (6.25)
Absence of equipment		
- Inadequate cerebral blood flow during temporary clip	N	1 (6.25)

R = Recover within 24 hours

N = Not recover within 24 hours

Table 4. Suggestive corrective strategy

Strategy	Number (%)
Improved supervision	4 (25.0)
Clinical practice guideline	3 (18.75)
More manpower	2 (12.5)
Additional training	2 (12.5)
Improved communication	2 (12.5)
More equipment provided	2 (12.5)
Quality assurance activity	1 (6.25)
Other	1 (6.25)

tive surveys which the report is made after the occurrence. Some information are perhaps reported with less consideration and count missing which is probably underestimated. The main drawbacks of data collection

are potential bias which leads to selection. We tried to diminish by an extensive introductory phase and emphasizing throughout the study the importance of submitting all cases. We performed the protocol explaining the definition, the criteria, invent a data entry system and modify the process of peer review to improve quality assurance reliability for ensuring the correction and value.⁽¹¹⁾ The main disadvantage of this qualitative study is the lack of a comparative group to determine the relative risk. The occurrence and the information obtained are the limitation. The further quantitative project should be followed.

In previous study there were large variation in the incidence of post operative convulsion as mentioned earlier but we find some interesting issues need to be addressed. Koren G et al reported two neonate suffered from generalized seizures during the course of intravenous morphine sulfate for post operative analgesia.⁽¹²⁾ Pirotta D et al reported a self limiting convul-

sion following the institution of an axillary brachial plexus block with levobupivacaine.⁽¹³⁾ Rozentsveig V et al reported convulsion after peribulbar anesthesia for cataract surgery⁽¹⁴⁾ and Rincon E et al reported convulsion after EMLA (Eutectic Mixture of Local Anesthetics) application in a pediatric patient.⁽¹⁵⁾ However, the comparison of our results with these literatures is hardly enable due to a marked difference in methodology.

The incidences from each local site in this study were not similar because of the type and size of the hospital. In addition, they can not suffice to differentiate one hospital or practice from another with respect to quality. The rare events can not be used to assess the performance of an individual physician or department of anesthesia where sound practice patterns result in safe care provided to the vast majority of patients.⁽⁶⁾

Our results showed that anesthesia was the minor factor comparing to surgical and patient related factors. Majority of incidents were preventable or partially preventable as the results from previous studies^(2,16). It is possibly realized that the complications mostly occurred during the post anesthetic period and the prognosis was poorer when it occurred on the wards than in locations where the patients were more closely supervised.⁽¹⁷⁾

In the aspect of anesthesia, human factors contributed over 70% to the anesthetic related death⁽⁴⁾ which reflected what we found in this study. In 1980, seizure following intracranial surgery was reported due to insufficient loading dose of anticonvulsant to ensure the therapeutic levels.⁽⁹⁾ In 1992, there were 7 cases of mistaken injections, 1 case was given anesthetics by a relatively inexperienced anesthetist but none had a fatal outcome.⁽²⁾ In 1997, there were 26 reported seizures related to regional anesthesia frequently after performing peripheral block⁽⁵⁾. Unfortunately, definitions of human related factors are not yet equivocal.

The risk factors of perioperative convulsion pertaining to surgical and pre-existing factors of the patient are discussed in some literature.^(2,4) The risk is increased in neurosurgery⁽⁹⁾, liver transplantation⁽¹⁸⁾ and open heart surgery.⁽¹⁰⁾ Moreover, the condition of the patients themselves: eg. age, previous central nervous system infection⁽¹⁹⁾, pharmacodynamic variability of target tissues in brain can superimpose the risk.⁽²⁰⁾

In summary, among the three risk factors; anesthesia, surgery and patients coordinated with contributing factors, they should be recognized and be candidates for developing the preventive corrective

strategy to improve quality and safety. The preventive recommendation from the results of this study is very important and should be officially implemented to achieve the quality in anesthesia practice and demonstrate the improving of health care system. Although this is the first initiative studying perioperative convulsion and the anesthetic contributing risk factors but we performed as a multidisciplinary, multicenter study, we hope that this study will act on the catalyst for projects represented in the collaboration research network in the future.

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การศึกษาอุบัติการณ์ภาวะชั้ระหว่างและหลังการให้ยาระงับความรู้สึกในประเทศไทย

ภูพิงค์ เอกะวิภาต, มะลิ รุ่งเรืองวานิช, วรณี เล็กประเสริฐ, สุรรัตน์ ศรีสวัสดิ์

วัตถุประสงค์: เพื่อประเมินอุบัติการณ์การเกิดภาวะชั้ระหว่างการผ่าตัดและภาวะชั้หลังการผ่าตัดภายใน 24 ชั่วโมง ผลการรักษา ปัจจัยเสี่ยง ปัจจัยที่มีส่วนทำให้เกิดความเสี่ยงในภาวะชั้เหล่านั้นๆ รวมถึงแนวทางในการแก้ไขภาวะดังกล่าว

วัสดุและวิธีการ: เป็นการศึกษาแบบพรรณนา เก็บข้อมูลในโรงพยาบาล 4 ระดับ 20 โรงพยาบาล ทั่วประเทศไทย ตั้งแต่ 1 มีนาคม พ.ศ. 2546 ถึง 28 กุมภาพันธ์ พ.ศ. 2547 โดยเลือกเฉพาะข้อมูลของผู้ป่วยเกิดภาวะชั้ระหว่างและหลังการผ่าตัด 24 ชั่วโมง จากจำนวนผู้ได้รับยาระงับความรู้สึกทุกราย ตามการศึกษาของ THAI Study บันทึกข้อมูลด้านประชากร เหตุการณ์ที่เกิดขึ้น ผลการรักษา ปัจจัยเสี่ยง และปัจจัยที่เอื้อให้เกิดความเสี่ยงนั้น ตลอดจนแนวทางแก้ไข โดยเน้นในส่วนที่เกี่ยวข้องโดยตรงกับการให้ยาระงับความรู้สึก

ผลการศึกษา: จากจำนวนผู้ป่วย 172,592 ราย มีผู้ป่วยที่เกิดภาวะชั้หลังผ่าตัด 3.1 รายต่อผู้ป่วย 10,000 คน ผู้ป่วยส่วนใหญ่ ร้อยละ 73.59 สามารถฟื้นตัวภายใน 24 ชั่วโมงหลังการผ่าตัด ปัจจัยเสี่ยงที่พบบ่อยเกิดจาก ภาวะทางศัลยกรรม ร้อยละ 67.92 และ ปัจจัยจากตัวผู้ป่วย ร้อยละ 54.72 ส่วนภาวะทางวิสัญญีวิทยา พบได้เป็นส่วนน้อยเพียงร้อยละ 30.19 ปัจจัยที่มักก่อให้เกิดความเสี่ยงที่เกี่ยวข้องกับงานด้านวิสัญญีวิทยา ได้แก่ การให้ยาผิด เช่น ผิดทาง ผิดชนิด หรือผิดเวลา ร้อยละ 43.75 และความบกพร่องของบุคลากร เช่น การดูแลไม่เพียงพอ ขาดความรู้ การติดต่อสื่อสารที่ไม่มีประสิทธิภาพ ร้อยละ 43.75 แนวทางแก้ไขที่สำคัญได้แก่ การให้คำปรึกษา และการสร้างแนวทางเวชปฏิบัติ

สรุป: อุบัติการณ์เกิดภาวะชั้หลังผ่าตัดเท่ากับ 3.1 รายต่อผู้ป่วย 10,000 คน ภาวะทางวิสัญญีวิทยาเป็นปัจจัยเสี่ยงที่เกิดขึ้นได้น้อย สาเหตุสำคัญได้แก่การให้ยาผิด และความบกพร่องของบุคลากร
