The Thai Anesthesia Incidents Monitoring Study (Thai AIMS) of Adverse Events after Spinal Anesthesia: An Analysis of 1,996 Incident Reports

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Background: *To study the incidents of complications, adverse events and anesthetic profiles of spinal anesthesia from primary to tertiary hospitals across Thailand.*
Material and Method: *The present study is a descriptive research design. Participating anesthesia providers are requested to report the standardized incident reporting form as soon as they find the predetermined adverse or undesirable events during anesthesia until 24 hours after the operation. Data from the incident report were reviewed and analyzed to identify contributing factors and preventive strategies by consensus by three-peer reviewers. The objections were discussed and the decision was made in order to achieve general agreement.*
Results: *One hundred and sixty-seven cases adverse events after spinal anesthesia were reported from fifty-one hospitals across Thailand. Eighty-five cases (50.9%) were male; eighty-two cases (49.1%) were female. Seventy cases (41.9%) occurred in patients whose age was more than 60 years. One hundred and thirty-one cases (78.4%) had ASA I and II, seventy cases (41.9%) occurred spontaneously whereas ninety-seven cases (58.1%) were considered as preventable. Most of the incidents (74.4%) were bradycardia (HR < 50 beats per minute). The others were hypotension (18.6%), respiratory complications (hypoxia and pulmonary edema) (5.4%), myocardial infarction (3.6%), and cardiac arrest (6.6%). Most of the incidents (88.6%) were detected by EKG, pulse oximeter (64.7%), and NIBP (71.3%) respectively. Anesthetic factors and systemic factors that found to be involved in all cases were high spinal block, inadequate prehydration and delayed resuscitation. Most of the contributing factors were inappropriate decision making (45%), inexperienced performers (20%), inadequate preoperative evaluation and preparation (19%). The incidents should be minimized by having prior experience, high awareness and experienced assistants available.*

For immediate outcome that occurred within 24 hours, eighteen cases (10.8%) had major physiological change such as hypoxia, pulmonary edema, myocardial infarction or neurological deficit. Ten cases (6%) died within 24 hours and one case (0.6%) had cardiac arrest intra-operative period. For long term outcome within 7 days, one hundred and fifty-seven reported cases (94%) had complete recovery; fourteen cases (8.4%) had prolonged hospital stay and ventilatory days.
Conclusion: *To minimize the adverse events after spinal anesthesia, the authors suggest corrective strategies which include established guideline practice, additional training, improved supervision and having quality assurance activity in each hospital.*

Keywords: *Adverse events, Spinal anesthesia, Bradycardia, Cardiac arrest, Hypotension, Myocardial infarction*

J Med Assoc Thai 2009; 92 (8): 1033-9
Full text. e-Journal: *http://www.mat.or.th/journal*

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Spinal anesthesia is one of most preferable anesthetic practice because of its predictability, low complication rate, and satisfactory results. Although severe complications with incomplete recovery are very rare; the incidence of adverse events such as bradycardia, hypotension remains common and can lead to serious complications *i.e.* cardiac arrest or death[1]. In addition, serious cardiac conditions occurred in association with spinal anesthesia have been reported. The Royal College of Anesthesiologists of Thailand initiates the Thai Anesthesia Incident Monitoring Study (Thai AIMS) to study the anesthetic adverse outcome and investigate incidents of anesthesia related complications which included spinal anesthesia. The present study also aimed to identify contributing factors, factors minimize incidents and suggested corrective strategies.

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 June 2007 from fifty one hospitals across Thailand[2,3].

After being approved by each institutional ethical committee, the specific spinal anesthesia related adverse events during 24 hours postoperative period were detected and reported as soon as possible. These included bradycardia, hypotension, suspected myocardial infarction or infarction, cardiac arrest, neurological complication, respiratory complication etc. Bradycardia in the present study was defined as heart rate less than 50 beats per minute and hypotension was defined as systolic blood pressure below 70 mmHg. The patient profiles, surgical profiles, anesthetic profiles and the description of incidents were recorded. Each incident report will be reviewed by three anesthesiologists. Any disagreements were discussed and made the decision in order to achieve consensus.

Results

During the period from January to June 2007, one hundred and sixty seven adverse events were reported from fifty one hospitals across Thailand. Eighty-five cases (50.9%) were male; eighty-two cases (49.1%) were female. Seventy cases (41.9%) occurred in patients whose age more than 60 years. Most of the events occurred in patient weight between 50-70 kilograms and height between 150-165 centimeters which were shown in Table 1. One hundred and thirty-one cases (78.4%) had ASA physical status 1 and 2. For the etiology of adverse events, seventy cases (41.9%) occurred spontaneously whereas ninety-seven cases (58.1%) were considered as preventable which eighty cases (47.9%) were considered as knowledge-based human error, fifteen cases (9%) were rule based, and two cases (1.2%) were skill based human error as described in Table 2.

Most of the incidents (74.4%) were bradycardia (HR < 50 beats per minute). The other adverse events were hypotension (18.6%), respiratory complications (hypoxia and pulmonary edema) (5.4%),

Table 1. Demographic data of patients and ASA physical status classification

Characteristics		Number of incidents (%)
Gender	Male	85 (50.9%)
	Female	82 (49.1%)
Age (yr)	13-20	7 (4.2%)
	21-40	49 (29.3%)
	41-60	41 (24.6%)
	61-80	46 (27.5%)
	> 80	24 (14.4%)
Weight (kg)	< 50	25 (15.0%)
	50-70	113 (67.7%)
	71-100	28 (16.8%)
	> 100	1 (0.6%)
Height (cm)	< 150	14 (8.4%)
	150-165	121 (72.5%)
	> 165	32 (19.2%)
ASA physical status	1	63 (37.7%)
	2	68 (40.7%)
	3	36 (21.6%)
	4	0

Values shown as frequency (%)

Table 2. Description of causes of adverse events after spinal anesthesia

Causes of adverse events	Frequency (%)
Spontaneously, incidentally unpreventable	70 (41.9%)
Human error	97 (58.1%)
Rule-based	15 (9.0%)
Knowledge-based	80 (47.9%)
Skill-based	2 (1.2%)

Values shown as frequency (%)

myocardial infarction (3.6%), and cardiac arrest (6.6%). Most of the incidents were detected by EKG (88.6%), pulse oximeter (64.7%), and also NIBP (71.3%) respectively. Anesthetic factors and systemic factors that found to be involved in all cases were high spinal block, inadequate prehydration and delayed resuscitation.

The immediate outcome is the adverse events that occurred within 24 hours. One hundred and twenty seven (76%) had minor physiologic change. Eighteen cases (10.8%) had major physiologic change such as hypoxia, pulmonary edema, myocardial infarction or neurological deficit. Ten cases (6%) died within 24 hours and one case (0.6%) had cardiac arrest intra-operative period as described in Table 3. Among the long term outcome that occurred within 7 days, one hundred and fifty seven reported cases (94%) had complete recovery. Fourteen cases (8.4%) had prolonged hospital stays and ventilatory support as described in Table 3.

Most of the contributing factors were inappropriate decision making (45%), inexperienced performers (20%), inadequate preoperative evaluation and preparing as described in Table 4. Most of the minimizing factors were prior experience (32.9%), high awareness (26.9%) and experienced assistants available (15.6%) as described in Table 5. Most of the corrective strategies were guideline practice (75.4%), additional training (12.6%) and improved supervision (12.6%) as described in Table 6.

Table 3. The outcome of adverse events after spinal anesthesia

Adverse event	Frequency (%)
Minor physiological change (*i.e.* bradycardia, hypotension)	127 (76.0%)
Unplanned ICU admission	11 (6.6%)
Major physiological change	
RS (*i.e.* hypoxia, pulmonary edema)	9 (5.4%)
CVS (*i.e.* myocardial infarction)	6 (3.6%)
Neuro (*i.e.* neurological deficit)	3 (1.8%)
Death	10 (6.0%)
Cardiac arrest	1 (0.6%)
Complete recovery	157 (94.0%)
Prolonged hospital stay and ventilatory support	14 (8.4%)
Death	10 (6%)

Values shown as frequency (%)

Table 4. The contributing factors of adverse events

Factors	Frequency (%)
Inappropriate decision making	75 (44.9%)
Inexperienced performers	34 (20.4%)
Inadequate preoperative evaluation and preparing	33 (19.8%)
Emergence cases	12 (7.2%)
Fatigued	8 (4.8%)
Inadequate of blood component	4 (2.4%)
Poor equipment	4 (2.4%)

Table 5. Factors minimizing incidents

Factors	Frequency (%)
Prior experience	55 (32.9%)
High awareness	45 (26.9%)
Experienced assistants available	26 (15.6%)
Guideline practice	22 (13.2%)
Monitoring available	20 (12%)
Improved training	10 (6%)
Improved consulting system	10 (6%)

Table 6. Suggested corrective strategies

Corrective strategies	Frequency (%)
Guideline practice	126 (75.4%)
Additional training	21 (12.6%)
Improved supervision	21 (12.6%)
Established quality assurance activity	18 (10.8%)

Discussion

Spinal anesthesia causes peripheral vasodilation and decreases venous return which leads to hypotension[1]. Moreover, it causes bradycardia as well by activating cardiac reflex such as Bezold Jarisch, Bainbridge reflex or by blocking cardiac accerelator[4]. Hypotension and bradycardia are common complications after spinal anesthesia which can lead to cardiac arrest[5,6]. In the present study, 74.4% of all reported complication was bradycardia, 18.6% was hypotension. Most of the cases were well managed without serious complications: 10.8% was considered to be a major physiological change, 5.4% was respiratory problems (hypoxia, pulmonary edema), 3.6% was cardiovascular problems (myocardial infarction), 1.8% was neurological problems (neurological deficit) and 8.4% of the reported cases needed prolonged hospital stay and ventilatory support. All the cases, which developed neurological problems, experienced complete recovery.

Ten cases (6%) of the reported cases died within 24 hours, seven cases were elderly patients who had multiple systemic diseases such as hypertension, diabetes mellitus, cardiac arrthymias and had severe hypotension during bone cementing in a case of total hip arthroplasty surgery. The other factors possibly were inadequate preoperative hydration and preparation, delayed treatment of hypotension and inadvertent high spinal anesthesia in two cases. One case had received both intrathecal morphine by the anesthesiologist and also intra-articular morphine by the orthopedic surgeon in total knee arthroplasty surgery. The patient developed respiratory arrest in the ward possibly due to synergistic effect of spinal and intra-articular morphine. One case underwent TUR-P surgery and had severe hypotension and cardiac arrest in the recovery room. By retrospective review, the patient had diagnosis of abdominal aortic aneurysm for many years which might rupture at the immediate postoperative period. One case had severe hypotension during massive blood loss in total hip arthroplasty surgery that was considered as both surgical and anesthetic death. Unfortunately, one case had cardiac arrest intraoperatively from over sedation and delayed treatment of hypotension and hypoventilation. He received fentanyl, diazepam and then ketamine because of inadequate spinal anesthesia. In conclusion, anesthetic related factors were contributed in ten cardiac arrest cases which the authors should reconsider about our practice *e.g.* the pre-anesthetic preparation and intra-operative management especially in elderly patients undergoing hip arthroplasty surgery with possibly filing cement during procedure. How to take care of the patients who had inadequate spinal anesthesia and the importance of communication between anesthesiologists and surgeons in cases of intrathecal opioid injection were other interesting considerations. In the Thai Anesthesia Incidents Study (THAI Study), a total of 11 cardiac arrests were reported with an incidence of 2.7:10000 spinal anesthetics with a high mortality rate[7]. The present study also confirmed the importance of close monitoring of patients during anesthesia.

In the present study, the incidence of bradycardia is 74.4% which is the majority of adverse reactions reported. Eighty cases (47.9%) were caused by inadvertent high spinal anesthesia, twenty-one cases (12.6%) were patients who had been taking beta blocking agent, and twenty-three cases (13.8%) were patients who did not have adequate preload. It is well established that vagal responses can be triggered by decreasing in preload. By the way, spinal anesthesia causes peripheral vasodilatation, decreased venous return. Activation of Bezold-Jarisch reflex or other reflex are more noticeable in the cases of inadequate preload volume[4,6]. Risk factors for bradycardia and cardiac arrest during spinal anesthesia are sensory block at the level above the T6 dermatome, which included cardiac acclerater fibers; high vagal tone such as that in a young age group; baseline heart rate < 60 beats/min and who were treated with beta-blocking agents are the patients who must be very carefully monitored[8-11].

Mojica et al revealed an increase of 25% in the incidence of spinal induced hypotension and 47% in the incidence of cardiovascular side effects for each increment of one segment in peak sensory block height. Higher level of sensory block correlates with higher cephalic spread of sympathetic blockade, greater decrease in venous return and cardiac output. In contrast, lower level of sympathetic blockade results in compensatory vasoconstriction in the upper extremities and decreases risk of spinal anesthesia induced hypotension. Their study also showed that administering crystalloid at the time of spinal block had a beneficial effect in preventing cardiovascular side effects as compared with administering crystalloid before spinal block because it provides additional intravascular fluids in the period of increase risk of cardiovascular side effect. Moreover, they found a decrease incidence of hypotension in 30-39 year old patients and increasing risk in younger as well as older patients which might be explained by a change in autonomic function and decrease cardiac reserve[12]. In the present study, the proportion of hypotension was 18.6% and related to patient factors, surgical factors and also anesthetic factor *e.g.* elderly patients (10%), surgical bleeding (5%) and also high spinal anesthesia.

Hypovolemia hastens not only classic vagal symptoms, but also causes cardiac arrest in healthy patients. Patients with risk factors for bradycardia or those with other vagal symptoms may be at increased risk for cardiac arrest during spinal anesthesia, so spinal anesthesia may not be the best technique for a patient with vagotonia or for a procedure that rapid blood loss is probable. If volume preloading is not enough to keep hemodynamic status, a vasopressor should be given early[13,14].

In addition, an over sedation during spinal anesthesia should be reconsidered. If patients have signs and symptoms such as discomfort or restlessness, the cause must be promptly evaluated.

In the present study, one case received diazepam and thiopenthal during restlessness that lead to respiratory compromised and one case received fentanyl, diazepam and ketamine as described above.

However, the limitation of the sensory blockage, correction of pre-operative hypovolemia and proper positioning the patient are fundamental prevention. Moreover, careful observation, close monitoring and effective resuscitation are very important in order to increase the safety of spinal anesthesia[14,15].

Hypotension which occurs in 15-33% is one of the most frequent side effects of spinal anesthesia. Many studies have been conducted concerning prehydration and therapy of hypotension after spinal anesthesia. Predictions of these events, however, have been addressed by only a few authors for spinal anesthesia. However, Carpenter et al described hypotension with an incidence of 33% in their study[15]. In 1989 Racele et al evaluated patients with known hypertension and found that risk for decrease in blood pressure was nearly twofold[14,15].

Transient Neurological Symptoms (TNS) are described as a syndrome of pain or dyesthesia in the lower extremities after administration of are uncomplicated spinal anesthetics. The symptoms usually appear within a few hours (up to 24 hours) after full recovery from spinal anesthesia and are self-limiting, usually with resolution by the second to fifth postoperative day. The pain is located in the gluteal area with radiation to both lower extremities. A systematic review of randomized, controlled trial comparing lidocaine with other local anesthetics to predict the frequency of TNS and neurologic complications after spinal anesthesia confirmed that lidocaine was associated with TNS more frequently than other local anesthetics (bupivacaine, mepivacaine)[16]. In the present study, the incidence of TNSs is 1.8%, located in the gluteal area with radiation to both lower extremities and all were recovered within 7 days.

In conclusion, spinal anesthesia remains an essential part of anesthesia, which carefully practice, would minimize adverse events, morbidity and also mortality along with corrective strategies including guideline practice, additional training, improved supervision and established quality assurance activity at each institute.

Acknowledgements

The present 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. We wish to thank all staffs of 51 Departments of Anesthesia who completed the adverse incident forms part imported in this study.

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โครงการเฝ้าระวังภาวะแทรกซ้อนจากการฉีดยาชาเข้าช่องไขสันหลังในประเทศไทยจากรายงานอุบัติการณ์ในผู้ป่วย 1,996 ราย

ปิยมาศ สิริวรารมย์, ธนิต วีรังคบุตร, เนตร หังสวณิช, พรเทพ เปรมสำราญ, วิมลรัตน์ ศรีราช

ภูมิหลัง: *การศึกษานี้เป็นส่วนหนึ่งของโครงการเฝ้าระวังภาวะแทรกซ้อนทางวิสัญญีในประเทศไทย โดยการรายงานอุบัติการณ์จากโรงพยาบาลชุมชน โรงพยาบาลทั่วไป โรงพยาบาลตติยภูมิ และโรงพยาบาลมหาวิทยาลัยทั่วประเทศไทย โดยมีวัตถุประสงค์เพื่อศึกษาอุบัติการณ์ของภาวะแทรกซ้อน ผลข้างเคียง และข้อมูลทั่วไปทางวิสัญญีของผู้ป่วยที่ได้รับการฉีดยาชาเข้าช่องไขสันหลังสำหรับการผ่าตัด*

วัสดุและวิธีการ: *เป็นการศึกษาเชิงพรรณนาแบบรายงานอุบัติการณ์ตามแบบฟอร์มของราชวิทยาลัยวิสัญญีแพทย์แห่งประเทศไทย ในผู้ป่วยที่ได้รับการฉีดยาชาเข้าช่องไขสันหลังจากโรงพยาบาล 51 แห่งในประเทศไทย ตั้งแต่เดือนมกราคม ถึง มิถุนายน ในปี พ.ศ. 2550 และนำอุบัติการณ์ของภาวะแทรกซ้อน ผลข้างเคียงตลอดจนเหตุการณ์ไม่พึงประสงค์ที่เกิดขึ้นกับผู้ป่วยในห้องผ่าตัดจนถึง 24 ชั่วโมงหลังผ่าตัด มาศึกษาปัจจัยที่เกี่ยวข้องและหาแนวทางป้องกันโดยการลงความเห็นของวิสัญญีแพทย์ 3 คน*

ผลการศึกษา: *ได้รับการรายงานอุบัติการณ์ในผู้ป่วยที่ได้รับการฉีดยาชาเข้าน้ำไขสันหลัง จำนวน 167 ราย เป็นผู้ป่วยชายจำนวน 85 ราย (ร้อยละ 50.9), ผู้ป่วยหญิง 82 ราย (ร้อยละ 49.1) ผู้ป่วยอายุมากกว่า 60 ปี จำนวน 70 ราย (ร้อยละ 41.9) โดยจำนวน 131 ราย (ร้อยละ 78.4) จัดอยู่ใน ASA 1 และ 2 และเมื่อพิจารณาจากภาวะแทรกซ้อนทั้งหมดพบว่าอุบัติการณ์จำนวน 70 ราย (ร้อยละ 41.9) เกิดขึ้นได้เอง ในขณะที่จำนวน 97 ราย (ร้อยละ 58.1) สามารถป้องกันการเกิดอุบัติการณ์ได้ อุบัติการณ์ส่วนใหญ่ ได้แก่ ภาวะหัวใจเต้นช้าผิดปกติ (น้อยกว่า 50 ครั้งต่อนาที) จำนวนร้อยละ 74.4 อุบัติการณ์อื่น ๆ ได้แก่ ความดันเลือดต่ำ (ร้อยละ 18.6) ภาวะแทรกซ้อนทางระบบหายใจ เช่น ขาดออกซิเจนและปอดบวมน้ำ (ร้อยละ 5.4) หัวใจขาดเลือด (ร้อยละ 3.6) และหัวใจหยุดเต้น (ร้อยละ 6.6) ส่วนใหญ่สามารถตรวจพบได้โดยเครื่องวัดคลื่นไฟฟ้าหัวใจ (ร้อยละ 88.6) เครื่องวัดระดับออกซิเจนในเลือด (ร้อยละ 64.7) และเครื่องวัดความดันเลือด (ร้อยละ 71.3) ปัจจัยทางวิสัญญี และปัจจัยอื่น ๆ ที่เกี่ยวข้อง ได้แก่ ระดับของการชาสูงเกินปกติ (high spinal anesthesia) การได้รับสารน้ำไม่เพียงพอและการแก้ไขภาวะแทรกซ้อนช้าเกินไป*

ปัจจัยของผู้ให้การระงับความรู้สึกที่มีผลเกี่ยวข้องมากที่สุด ได้แก่ การตัดสินใจไม่เหมาะสม (ร้อยละ 45) ขาดประสบการณ์ (ร้อยละ 20) ขาดการประเมินและเตรียมผู้ป่วยอย่างเหมาะสม (ร้อยละ 19) ซึ่งการมีประสบการณ์มาก่อน มีความระแวดระวัง และมีผู้ช่วยที่มีประสบการณ์ ควรช่วยลดการเกิดอุบัติการณ์ได้

จากการติดตามผลข้างเคียงที่เกิดภายใน 24 ชั่วโมง 18 ราย (ร้อยละ 10.8) มีการเปลี่ยนแปลงทางสรีรวิทยาอย่างรุนแรง เช่น ขาดออกซิเจนในเลือด, ปอดบวมน้ำ, หัวใจขาดเลือด หรือบกพร่องทางระบบประสาท มีผู้ป่วยจำนวน 10 ราย (ร้อยละ 6) เสียชีวิตภายใน 24 ชั่วโมงหลังผ่าตัด และจำนวน 1 ราย (ร้อยละ 0.6) มีภาวะหัวใจหยุดเต้นในห้องผ่าตัด ส่วนผลในระยะยาวที่เกิดขึ้นภายใน 7 วัน พบว่า 157 ราย (ร้อยละ 94) หายเป็นปกติ โดยจำนวน 14 ราย (ร้อยละ 8.4) ใช้เครื่องช่วยหายใจและอยู่โรงพยาบาลนานกว่าที่คาดการณ์ไว้

สรุป: *มาตรการลดอุบัติการณ์ของภาวะแทรกซ้อนของการฉีดยาชาเข้าช่องไขสันหลัง ได้แก่ แนวทางเวชปฏิบัติ การฝึกอบรมเพิ่มเติม มีผู้ดูแลและควบคุมการปฏิบัติงาน ตลอดจนมีกระบวนการคุณภาพ*