The Thai Anesthesia Incidents Study (THAI Study) of Pulmonary Aspiration : A Qualitative Analysis

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Objectives: *To examine the risk factors, outcomes, and contributing factors associated with perioperative pulmonary aspiration.*
Material and Method: *Pulmonary aspiration incidents were extracted from the Thai Anesthesia Incidents Study (THAI Study) database conducted between March 1, 2003, and February 28, 2004, and analyzed using descriptive statistics.*
Results: *Thirty — two incidents of aspiration were reported. Passive regurgitation occurred more frequently than active vomiting. Aspiration occurred more commonly in elective rather than emergency surgery, with 59% of incidents taking place during the induction of anesthesia and intubation period. While a major immediate physiological disturbance was common, long term morbidity was not. Death ensued in 5 cases, most of which had significant co — morbidities. Most cases (62.5%) were appropriately treated. The majority of incidents occurred in ASA class 2 (56.3%), age group 15 — 64 years (59.4%), non obese (92.9%) and non — difficult intubation (71.9%). Most cases were incomplete fasted or had prolonged gastric emptying time. Nasogastric aspiration and rapid sequence induction with cricoid pressure were infrequently used (12.5, 25%). Factors reported as contributing to the incidents included failure of technique and error of judgement. Additional training, continuing medical education and quality assurance tended to minimize the incidents.*
Conclusion: *Aspiration occurred commonly in patients with incomplete fasted or had prolonged gastric emptying time and underwent elective surgery. Additional training, continuing medical education and quality assurance tended to minimize the incidents.*

Keywords : *Pulmonary aspiration, Anesthesia, Multicenter study, Complication, Adverse outcomes*

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Aspiration of gastric contents in perioperative period remains a risk in modern anesthesia. The incidence of aspiration has seen little change in the last few years. A study of a Scandinavian Hospital in 1986 suggested that the incidence of aspiration varied between 0.7 and 4.7 per 10,000 general anesthetics[1]. One decade later, a report from a Norwegian hospital suggested that the incidence was 2.9 per 10,000[2] . Studies from the Mayo Clinic indicated that the incidence of aspiration is similar (3.1 per 10,000) [3].

Greater understanding of the pathophysiology of gastric motility and factors influencing normal function has reduced this complication in recent years. In addition, fasting guidelines are being relaxed to allow patients free access to fluid closer to the induction of anesthesia[4]. Several medications such as antacid,

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H_2 — blocker and proton pump inhibitor are proposed as aspiration prophylaxis[5,6].

In Thailand, there are variations of anesthetic personnel and monitoring equipment, including clinical guidelines for anesthetic management. Incidence of pulmonary aspiration was 2.7 per 10,000 according to the Thai Anesthesia Incidents Study (THAI Study). This study aims to assess immediate and long term outcomes of pulmonary aspiration, the appropriateness of event management, and to identify clinical risk factors, contributing factors and corrective strategies.

Material and Method

The Thai Anesthesia Incidents Study (THAI Study) is a multi — centered study including 7 university hospitals, 5 tertiary care hospitals, 4 secondary care hospitals and 4 district hospitals. This study aimed to monitor the incidence of adverse events from March 1, 2003 to February 28, 2004. THAI Study was approved by the Instutional Ethical Review Board. Details of preanesthetic conditions, anesthetic management, intraoperative events and perioperative complications of consecutive patients within 24 hours were recorded on a standardized form (form 1).

Aspiration was considered to have occurred if any obvious nonrespiratory secretions were suctioned via a tracheal tube and/or there were signs of a new wheeze or crackles after an episode of regurgitation or vomiting and /or there was chest x — ray evidence of new pathology after an incident.

The detail of pulmonary aspiration was recorded by the attending anesthesiologist or nurse anesthetist and site manager. Then the recorded form (form 2) was reviewed by 3 peer reviewers to identify clinical risk factors, contributing factors and corrective strategies. Any controversy was discussed to achieve a consensus.

Each incident form was reviewed and relevant

Table 1. Patient characteristics (N=32)

	n	%
Sex		
Male	17	53.1
Female	15	46.9
ASA Physical status		
1	6	18.8
2	18	56.3
3	5	15.6
4	3	9.4
Age group(years)		
0-1	3	9.4
2-14	6	18.8
15-64	19	59.4
>64	2	12.5
BMI		
≤ 28	30	92.8
> 28	2	6.3
Difficult intubation		
Yes	8	25.1
No	23	71.9
Not stated	1	3.1
Disease attributed to prolonged gastric emptying time		
Yes	17	53.1
No	14	43.8
Not stated	1	3.1

Table 2. Detail of events

	n	%
Evidence of active or passive regurgiation		
Yes	24	75.0
No	6	18.8
Not stated	2	6.3
Material aspirated		
Bile	6	20
Clear fluid	7	23.3
Solid particle	1	3.3
Coffee ground	8	26.7
Blood	5	16.7
Not stated	3	10
X-ray finding after incident		
Clear X-ray	10	31.3
Bilateral changes	8	25.0
Right lung changes	3	9.4
Left lung changes	2	6.3
Not stated	9	28.1
Criteria for diagnosis		
A. Tracheal aspiration	14	43.8
B. Wheeze or rhonchi	7	21.9
C. Chest X-ray	4	12.5
D. A + C	1	3.1
E. B + C	1	3.1
F. A + B + C	1	3.1
G. Not stated	4	12.5

Table 3. Outcome of incident (N=32)

	Immediate outcome, n (%)	Long term outcome, n (%)
Death	1 (3.1)	4 (12.5)
Cardiac arrest	1 (3.1)	-
Major effect	16 (50.0)	5 (15.6)
Minor effect	4 (12.5)	-
Complete recovery	8 (25.0)	21 (65.6)
Not stated	2 (6.3)	2 (6.3)

factors entered into a Microsoft Excel spread sheet. Data were entered as originally recorded on the individual reports. Then the data were analyzed. Demographic data included age, sex, ASA status and co — morbidities. Details of events included type of anesthetic used, evidence of active vomiting and passive regurgitation, type of material aspirated, when the incident occurred, anti — aspiration prophylaxis, fasting status, effects of aspiration, type of airway in use, management after the incident and factors promoting and reducing the severity of the incident and its potential

Risk factors were categorized into patient, anesthetic, surgical and systematic factors. Patient risk factors included obesity, difficult intubation and disease attributed to prolong gastric emptying time. Anesthetic risk factors included fasting status, aspiration prophylaxis, premedication, anesthetic technique, type of airway used and rapid sequence induction with cricoid pressure. Surgical risk factors included type, position and site of surgery. Systematic risk factors included the level of hospital, anesthetic team leader and contributing factors. Because data were qualitative, descriptive statistics were performed

Results

Demographic data of the thirty — two pulmonary aspiration incidents reported are shown in Table

Table 4. Surgical factors (N=32)

	n	%
Type of surgery		
Elective	17	53.1
Emergency	14	43.8
Not stated	1	3.1
Position		
Supine	30	93.8
Lateral	1	3.1
Not stated	1	3.1
Site of surgery		
Abdomen		
- upper	10	31.3
- lower	5	15.6
Airway	5	15.6
Extremity	3	9.4
Endoscope	3	9.4
Intracranial	2	6.3
Eye	1	3.1
Maxillofacial	1	3.1
Cesarean section	1	3.1
Perineal anal	1	3.1

1. The majority of incidents occurred in ASA class 2, age group 15 — 64 years, non-obese (BMI$\leq$ 28) and non difficult intubation. Diseases attributed to prolonged gastric emptying such as diabetes mellitus (9.4%) and renal failure (9.4%) were attributed to the incident

Passive regurgitation occurred more frequently than active vomiting. The type of material involved in the incident is shown in Table 2. The aspiration was mostly diagnosed by tracheal aspiration. Chest x — ray evidence of aspiration pneumonitis was dem onstrated in 13 patients (40.7%). Bilateral pathology was recorded more often than unilateral lung change (Table 2).

Within 24 hours following the aspiration events, eighteen patients (56.1%) had major physiological disturbance including one death (ASA 2E) and one cardiac arrest (ASA grade 4E). Twenty — four hours after the events, 21 (66%) patients completely recovered while death ensued in 4 cases (Table 3). There were deaths in ASA grade 3E and 4E.

Event management was evaluated, Twenty patients (62.5%) were adequately treated, 7 patients (21.9%) were inadequate treated but not hazardously whereas 3 patients received inadequate and hazardous treatment.

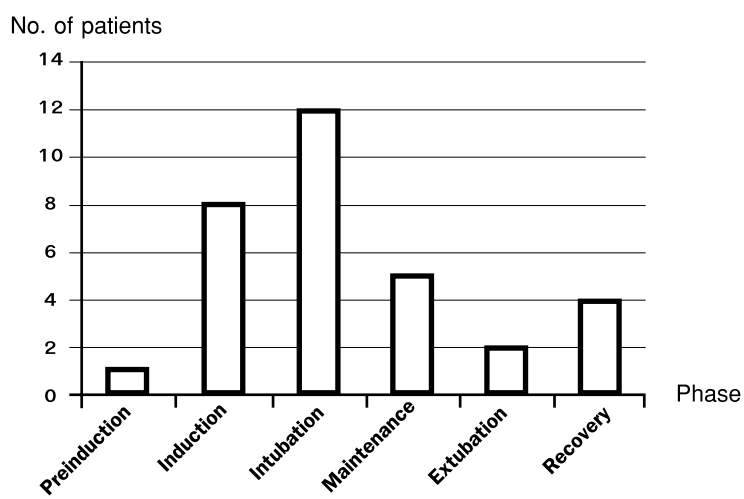

Fig 1. Period of aspiration

Table 5. Contributing factors (N=32)

	n	%
Human factors		
Presence	1	3.1
Knowledge	14	43.8
Inadequate care		
Inadequate preoperative evaluation	9	28.1
Inexperience	29	90.6
Fatigue	2	6.3
Lack of supervision	7	21.9
Communication failure	2	6.3
Equipment failure		
Presence	2	6.3
Function	3	9.4
Medical failure	0	0
Facility failure	0	0
Organization failure		
Inadequate guideline	7	21.9
Inadequate system of consultation	2	6.3
Inadequate referral system	0	0

Table 6. Corrective strategy (N=32)

	n	%
Quality assurance activity	26	81.3
Additional training	23	71.9
Improve supervision	23	71.9
Guideline practice	10	31.3
Improve communication	5	15.6
More manpower	4	12.5
Equipment maintenance	3	9.4
More equipment provided	2	6.3

According to risk factors related to anesthesia, 14 (43.8%) of the patients did not fast completely while 14 (43.8%). fasted adequately but had prolonged gastric emptying time. No anti — aspiration was performed on 4 patients (12.5%). Premedication such as benzodiazepine or narcotics was prescribed for 9 patients (28.2%).

The incidents occurred most frequently in university hospitals (21 from university hospital, 8 from tertiary care hospital and 3 from secondary care hospital). Twenty-nine (90.6%) anesthetic team leaders were anesthesiologists The ratio between experienced intubators and trainees was not different (anesthesiologist 9, nurse anesthetist 7, resident 7, anesthesia nurse trainee 5, others 4). Pulmonary aspiration mostly occurred during induction and intubation in patients receiving general anesthesia with tracheal intubation (Fig.1) Only 8 patients (25% of total incidents) received rapid sequence induction with cricoid pressure. A pulse oximeter was used on all patients during incidents whereas end tidal CO_2 monitoring was applied to 14 patients (43.8%)

As for surgical factors, aspiration incidents did not occur more frequently in emergency surgery. Most incidents occurred when patients underwent surgery in a supine position. The majority of patients underwent abdominal and airway surgery (Table 4) Aspiration incidents were documented to be preventable in 14 patients (43.8%) and partially preventable in 16 patients (50%). Anesthesia was considered to be the sole contribution factor in 10 patients (31.3%) and a combination with other factors in 19 patients (59.4%) Considering systems analysis, the three most important contributing factors included : inadequate care from inexperience, 29 (90.6%), and inadequate preoperative evaluation, 9 (28%), and inadequate knowledge 14 (43.8%) (Table 5). The majority of reports which proposed corrective strategies included quality assurance activity after the events, 26 (81.3%), additional training 23 (71.9%) and improvement of supervision 23 (71.9%) (Table 6).

Discussion

Data from THAI Study has shown that perioperative aspiration was infrequent. The incidence

of 1.9 per 10,000 was within the range of aspiration incidence in the Western world. However, the death rate in patients who aspirated was 15.6%, higher than the 3.8% of the Australia Incident Monitoring Study [7], 4.5% of the Mayo Clinic Study [3] and 4.6% of the Sweden Study [1]. Eighty percent of mortality cases were associated with increased severity of illness.

It has been suggested that the factors that contribute to the likelihood of aspiration include the urgency of surgery, airway problems, inadequate depth of anesthesia, use of the lithotomy position, gastrointestinal problems, depressed consciousness, increased severity of illness and obesity [6].

Results from our study indicated that aspiration occurred more frequently in low risk patient groups, elective cases, age 15 —94 years (59.4%). The incidence of aspiration in the ASA PS class 1 and 2 was three times more than that in ASA PS class 3 and 4. Most patients were not obesed; ninety — three percent has body mass index of 28 or less. Difficulty with intubation was found in only 25% of cases.

In this study, the relevant risk factors were attributed to gastrointestinal problems including disease with prolonged gastric emptying time (53%), inadequate fasting duration or sufficient fasting duration but with prolonged gastric emptying time (87.6%) and abdominal surgery (47%). These results also agreed with previous reports that diabetes mellitus [8,9] and abdominal pathology 10 [1] had a significant larger gastric volume and delayed gastric emptying time.

Similar to AIMS [7], the majority of incidents occurred at the induction and intubation periods, a significant proportion was presented during maintenance and recovery periods. Problems during induction and intubation can be compounded by airway difficulties and/or inadequate anesthesia. In this study, difficulty with intubation was reported in only 25% of the cases. As the majority of cases had inadequate fasting duration or prolonged gastric emptying time combined with reduction in esophageal tone from induction agents [11] and muscle relaxation [12,13], passive regurgitation may have occurred. In addition, the method to reduce gastric volume e.g. nasogastric aspiration and method to prevent pulmonary aspiration e.g. rapid sequence induction with cricoid pressure, were infrequently used. Therefore, the occurrence of incidents were not associated with difficulty in intubation and the experience of the intubator.

Antacid therapy or simple reduction of pH was not conclusive to prevent and/or optimize the incidents as there was not only gastric content aspirated but also other material (e.g., bile, solids, coffee ground or blood). There is a great variation in the prescription of antacid, H_2 antagonist and proton pump inhibitor [6,7]. Although it is possible to show that these drugs increase gastric pH and reduce gastric volume, there is no evidence to support their routine use because of the infrequent incidence of aspiration. Clinical trials have been conducted mostly in healthy patients and not in those patients who would likely regurgitate and aspirate. In this study, there was no report of using these drugs.

Several studies have investigated the safety of the laryngeal mask airway (LMA) with respect to airway protection and the risk of aspiration; there have been reports of pulmonary aspiration, though infrequently [14,15]. There were no aspirated cases using LMA in this report. Nonetheless, one case aspirated in spite of an endotracheal tube in situ.

Our results are consistent with previous reports [7,16] that human error contributed to a majority of all system failures. Technical error (fault of technique), knowledge — based error (error of judgement) and rule — based error (inadequate patient evaluation and preparation) were the most common contributing factors identified in this study. Technical errors can be aided by additional training such as the use of simulators, anatomical modes and other applied educational models. Knowledge — based errors can be reduced by quality assurance and continuing medical education to improve supervision, while rule — based error can be attenuated by the use of protocols and crisis management algorithm [7]. In this study, the majority of incidents occurred in university hospitals where there were a lot of trainees; therefore, experience and skill improvement were very important to reduce the risk of aspiration

In conclusion, this prospective review of 32 incidents has indicated that perioperative regurgitation and/or vomiting is associated with mortality. Incidents were infrequent, but associated with high mortality in patients with ASA class 3 or 4 with significant co-morbidities. Important risk factors were inadequate fasting duration, gastrointestinal pathology, nasogastric aspiration and rapid sequence induction with cricoid pressure. Factors to minimize the incidents included additional training, quality assurance, continuing medical education and protocol development.

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การศึกษาอุบัติการณ์สำลักเข้าปอดจากการให้ยาระงับความรู้สึกในประเทศไทย : การวิเคราะห์เชิงคุณภาพ

สุวรรณี สุรเศรณีวงศ์, ทรงยศ วลัยฤาชา, ธวัช ชาญชญานนท์, นิรันดร์ มั่นคง, เทวารักษ์ วีระวัฒกานนท์, มะลิ รุ่งเรืองวาณิช

วัตถุประสงค์: *เพื่อหาสาเหตุ ประเมินผลที่เกิด และปัจจัยที่เกี่ยวข้องกับอุบัติการณ์การใส่ท่อช่วยหายใจโดยไม่ได้วางแผนมาก่อนหลังการให้ยาระงับความรู้สึก*

วัสดุและวิธีการ: *ศึกษาข้อมูลผู้ป่วยที่มีภาวะสูดสำลักเข้าปอดหลังการให้ยาระงับความรู้สึกซึ่งคัดเลือกมาจาก ข้อมูลการศึกษาของราชวิทยาลัยวิสัญญีแพทย์แห่งประเทศไทยซึ่งรวบรวมตั้งแต่ 1 มีนาคม พ.ศ. 2546 ถึง 28 กุมภาพันธ์ พ.ศ. 2547 นำมาวิเคราะห์ทางสถิติเชิงพรรณนา*

ผลการศึกษา: *ผู้ป่วยที่เข้าเกณฑ์ 32 รายพบว่าการสูดสำลักเกิดระหว่างการสำรอกบ่อยกว่าการอาเจียน และพบในการผ่าตัดแบบ elective มากกว่าการผ่าตัดฉุกเฉิน ร้อยละ 59 เกิดระหว่างการนำสลบและการใส่ท่อ ช่วยหายใจ หลังการสูดสำลักมักพบการเปลี่ยนแปลงของร่างกายอย่างมากภายใน 24 ชั่วโมง แต่มักไม่พบหลัง 24 ชั่วโมง พบผู้ป่วยถึงแก่กรรม 5 ราย ส่วนใหญ่ผู้ป่วยมีโรคที่รุนแรงอยู่แล้ว ร้อยละ 62.5 ได้รับการรักษาอย่างเหมาะสม ส่วนใหญ่ภาวะนี้พบใน ASA class 2 (ร้อยละ 56.3), อายุ 15-64 ปี (ร้อยละ 59.4), ไม่อ้วน (ร้อยละ 92.9), และใส่ท่อหายใจไม่ยาก (ร้อยละ 71.9) ผู้ป่วยส่วนใหญ่งดน้ำ งดอาหารไม่ครบ หรือมี prolonged gastric emptying time นอกจากนี้ยังพบว่ามีการใช้ nasogastric aspiration หรือ rapid sequence induction with cricoid pressure น้อย (ร้อยละ 12.5, 25) ปัจจัยเชิงระบบที่เกี่ยวข้อง ได้แก่ การเลือกใช้เทคนิคไม่เหมาะสมและการตัดสินใจผิดพลาด วิธีการแก้ไขควรให้การฝึกอบรมเพิ่มเติม การให้ความรู้อย่างต่อเนื่อง และระบบประกันคุณภาพงานบริการ น่าจะช่วยลดอุบัติการณ์ได้*

สรุป: *ภาวะสูดสำลักเข้าปอดมักพบในผู้ป่วยที่ งดน้ำ งดอาหารไม่ครบ หรือมี prolonged gastric emptying time และมารับการผ่าตัดแบบ elective ส่วนใหญ่อาการมักหายภายใน 24 ชั่วโมง การฝึกอบรมเพิ่มเติม การให้ความรู้อย่างต่อเนื่อง และระบบประกันคุณภาพงานบริการ น่าจะช่วยลดอุบัติการณ์ได้*