Development and Validation of a Predictive Model for Difficult Tracheal Intubation in Thai Obese Patients

Miss Arunotai Siriusswakul

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การพัฒนาและประเมินความเที่ยงตรงของแบบจำลองสำหรับการพยากรณ์ ภาวะใส่ท่อหายใจยาก
ในผู้ป่วยอ้วนคนไทย

นางสาวอรุโณทัย ศิริอัศวกุล

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By	Miss Arunotai Siriusswakul
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Thesis Advisor	Associate Professor Ketchada Uerpairojkit, M.D.

Accepted by the Faculty of Medicine, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

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(Associate Professor Wimonrat Sriraj, M.D.)

อรุโณทัย ศิริอัศวกุล : การพัฒนาและประเมินความเที่ยงตรงของแบบจำลองสำหรับการพยากรณ์ภาวะใส่ท่อหายใจยากในผู้ป่วยอ้วนคนไทย. (Development and Validation of a Predictive Model for Difficult Tracheal Intubation in Thai Obese Patients) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: รศ. พญ. เกศชาดา เอื้อไพโรจน์กิจ, 61 หน้า.

การจัดการทางเดินหายใจในผู้ป่วยอ้วนที่มารับการระงับความรู้สึกเป็นสิ่งที่บุคลากรทางวิสัญญีให้ความสนใจ ในปัจจุบันการยังไม่มีวิธีการประเมินทางเดินหายใจที่สามารถบ่งชี้ว่าผู้ป่วยอ้วนรายใดมีความเสี่ยงต่อการจัดการทางเดินหายใจ แบบจำลองสำหรับการพยากรณ์ภาวะใส่ท่อหายใจยากที่มีเป็นแบบที่ใช้พยากรณ์ในผู้ป่วยทั่วไป ผู้วิจัยจึงทำการศึกษาแบบพหุสถาบันเพื่อสร้างแบบจำลองที่ได้จากการตรวจประเมินทางเดินหายใจก่อนการให้การระงับความรู้สึกและวางแผนประเมินแบบจำลองที่ได้โดยทดสอบใช้ในผู้ป่วยอ้วนอีกกลุ่ม

ผู้วิจัยได้ทำการศึกษาในโรงพยาบาล 4 แห่ง รวบรวมข้อมูลจากผู้ป่วยได้ 280 ราย คำจำกัดความภาวะใส่ท่อหายใจยากใช้ตามคำจำกัดความของ Adnet และคณะ โดย intubation difficulty scale (IDS) score > 5 หมายถึง ภาวะใส่ท่อหายใจยาก คะแนน ผู้ป่วยทุกรายได้รับการตรวจประเมินทางเดินหายใจเพื่อพยากรณ์ภาวะใส่ท่อหายใจยากดังนี้ มีลักษณะฟันบนคู่หน้าผิดปกติ, Modified Mallampati test, upper-lip bite test, การเคลื่อนไหวของกระดูกต้นคอทั้งก้มและเงย การวัดช่องห่างระหว่างฟันบนและฟันล่าง การวัดระยะ hyomental distance, thyromental และ sternomental distance, การวัดเส้นรอบคอและการวัดความยาวของคอ

ก่อนเริ่มทำการเก็บข้อมูล ผู้วิจัยหลักจะสอนผู้ช่วยเก็บข้อมูลในแต่ละสถาบันจนผลของการวัดมีค่าใกล้เคียงกันก่อน จากผลการศึกษาผู้วิจัยพบผู้ป่วยอ้วนที่มีภาวะใส่ท่อหายใจยากตามคำจำกัดความเพียง 3 ราย ผู้วิจัยจึงได้สร้างแบบจำลองสำหรับพยากรณ์การจัดการทางเดินหายใจที่มีความยุ่งยากแทน (IDS > 0) แบบจำลองดังกล่าวได้พัฒนาจากข้อมูลของผู้ป่วย 200 รายจากโรงพยาบาลศิริราช แบบจำลองสุดท้ายมีตัวแปรที่เกี่ยวข้อง 3 ตัว ได้แก่ เส้นรอบคอ ช่องห่างระหว่างฟันบนและฟันล่างและ Modified Mallampati test และเมื่อนำแบบจำลองที่ได้มาทดสอบความเที่ยงในผู้ป่วยอ้วนจำนวน 80 รายจากพหุสถาบัน ได้ผลค่าต่างๆ ดังนี้ sensitivity of 70.0%, specificity of 45.0% and accuracy of 57.5%

สาขาวิชา การพัฒนาสุขภาพ	ลายมือชื่อนิสิต ....
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KEYWORDS: DIFFICULT INTUBATION / PREDICTION / AIRWAY ASSESSMENT / RISK SCORE / OBESE

ARUNOTAI SIRIUSSWAKUL: DEVELOPMENT AND VALIDATION OF A PREDICTIVE MODEL FOR DIFFICULT TRACHEAL INTUBATION IN THAI OBESE PATIENTS. ADVISOR: ASSOC. PROF. KETCHADA UERPAIROJKIT, M.D., 61 pp.

The most concern of anesthetists in anesthesia for obese patients is airway management. Such bedside tests information is nowadays not capable of discriminate obese patients who have no outstanding features of problematic patients from non difficult conditions. Existing predictive models were developed for general, not specific to obese group. We conducted a multi-center to set up a practical new predictive model and to validate it using a separate set of patients. This observational study was conducted in 280 obese patients who were expected to not use alternative tools for first-line management in four hospitals. Difficult intubation was defined using an intubation difficulty scale (IDS) score > 5. Clinical assessment, including malformation of central teeth in the upper jaw, a modified Mallampati test, an upper-lip bite test, the range of motion of the neck (flexion and extension), the inter-incisor gap, the hyomental distance, the thyromental distance, the sternomental distance, the neck circumference, and the length of the neck, were examined in all patients.

The inter-observer reliability of raters was > 0.7 before initiation of the study. Overall, only three patients experienced difficult intubation during conventional endotracheal intubation. Logistic regression model for troublesome intubation (IDS > 0) was then developed based on 200 patients from Siriraj Hospital. The simplified final model comprised only three independent variables. It revealed that patients with bigger neck circumference had a higher risk of troublesome intubation with adjusted OR of 1.15 for one centimeter increment in NC. Decreased in one centimeter of inter-incisor gap increased the risk of troublesome intubation to 1.59 (95% CI: 1.03, 2.50). Regarding modified Mallampati test, class II and III had a higher risk of troublesome intubation compared to class I (adjusted OR of 2.20 and 3.68 respectively). The final logistic regression fit the data quite well with p-value from Hosmer-Lemeshow test of 0.254. To validate the final logistic regression model, this model was applied to another set of 80 patients. Probability of troublesome intubation for each subject was then calculated. Cut point of 0.45 resulted in the sensitivity of 70.0%, specificity of 45.0% and accuracy of 57.5% respectively.

Field of Study: Health Development Student's Signature ....

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CHAPTER I

Background and rationale

Obesity is a worldwide epidemic, and it becomes a growing health problem in Thai population. The prevalence of Thai adult obese, according to the obesity criteria reported by the World Health Organization, increased from 15-20%[1] in 1990 to 25 -30%[2] in 2011. The most concern of anesthetists in anesthesia for obese patients is airway management. Although there is no clear consensus that whether obesity per se is an independent risk factor for difficult intubation, obese patients have been thought to be at greater risk, when compare with general population.

The incidence of difficult intubation in obese subjects has been quoted varied from 1.8 to14.3%.[3,4,5] This incidence was much higher than the incidence of difficult intubation among Thai patients, which accounted for only 0.05%.[6] Adverse outcomes associated with the difficult airway include death, brain injury, cardiopulmonary arrest, unnecessary tracheostomy, airway trauma, and damage to teeth.[7] Obese patients have a number of physiologic alterations, such as increase oxygen consumption, decrease chest wall compliance and decrease functional residual capacity.[8] As expected in difficult situations, long intubation time or low oxygen saturation may be resulted in high risk of perioperative adverse events.

Patients' demographic such as age, body mass index, gender, comorbidities such as diabetic mellitus[9], obstructive sleep apnea[10], acromegaly, previous operations in the cervical spine, and history of difficult intubation or needed fiberoptic intubation were suggested predictors for the difficult intubation.[11] Shiga et al, reported a meta-analysis included 35 studies (50,760 patients), four types of tests included Mallampati classification (MP), thyromental distance (TM), sternomental distance (SM), inter-incisor gap (IIG) have been commonly used for prediction difficult intubation. However, each test yielded poor to moderate pooled sensitivity (22-62%), but good pooled specificity (82-97%).[12] Combination of each test or creating risk scores may provide an ideal method for predictive models of difficult intubation, which should have high sensitivity and specificity, minimal false positive and false negative. Some predictive models such as Wilson, Arne or Neguib models revealed good predictive performance for prediction of difficult intubation.[13]

The Mallampati classification, first described by Mallampati et al, has become the most well known and the most common diagnostic test for predict difficult intubation since 1985.[14] The scoring system subsequently revised by Samsoon and Young in 1987.[15] The modified Mallampati test (MMT) was assessed while patient sat with the head in the neutral position, the tongue maximally protruded without phonation. The test seemed to be useful in obese patients with usually have a big and large base of tongue in relation to the oral cavity. The test may possible indicate whether displacement of the tongue by the laryngoscope blade was likely to be easy or difficult. In many study, high Mallampati score (class III and IV) was independent risk factor of difficult intubation.[10,16,17]

Neck circumference (NC) was a screening measurement which could be used to identify patients with overweight or obesity. Men with NC ≥ 39.5cm and women with NC ≥ 36.5 cm were correlated with BMI ≥ 30 kg/ m^2, in a report from Israel.[18] A large amount of neck soft tissue could cause difficulty in airway management. In a study by Gonzalez et al, NC > 43 cm, measured at the level of the thyroid cartilage, was associated with difficult intubation (described as the intubation difficulty scale > 5) in patients with BMI ≥ 30 kg/ m^2.[5] Kim et al, also reported an association of neck circumference, measured at the level of cricoid cartilage, and difficult intubation in 123 Korean patients with BMI ≥ 27.5 kg/m^2. The incidence of difficult intubation in obese group was 13.8%. The ratio of neck circumference and thyromental distance (NC/ TM) ≥ 5 was a strong predictor of difficult intubation.[19] Other bedside tests such as TM, SM, or IIG were presented in literature related difficult airway in obese patients. However, the diagnostic performance of each predictor was not clear, there were some cut-off point. Such bedside tests information is nowadays not capable of discriminate obese patients who have no outstanding features of problematic patients from non difficult conditions; a new predictive model is needed. Existing models such as Wilson score[20] or Arné model[21] were developed for general, not specific to obese group. As a result, variables in the final model are not related to obese patients. In addition, some authors selected variables from history taking and physical examination simultaneously in the initial model. The selection may result in multicollinearity or interaction between variables in the model because patients' diseases are commonly the single factor determining the airway pathology. For example, severe diabetic mellitus is related with limited joint ability or stiff joint syndrome, Acromegaly is related with macroglossia, prognathism and abnormal glottic structure and rheumatoid arthritis is related with cervical spine abnormalities. Lastly, variables in the model were difficult to measure or interpret by trainees or non anesthesiologist personnel, leading to limitation of translation in clinical practice.

CHAPTER II

Literature review

In order to cover all the airway assessment which could predict difficult intubation, a review of the literature was performed using the search terms - ("difficult intubation" OR "difficult airway") AND ("prediction" or "risk factor" OR "predictive model") AND airway assessment AND obesity, and other combinations of these terms. Table 1 summarizes each method of airway assessment, definition and predictive performance from literature, which were not specific to obese patients. Table 2 summarizes literature which demonstrated bed side tests in obese patients. Existing prediction models are presented in Table 3-5. All models presented were not specific to obese patients.

Table 1: Methods of airway assessment tests, definition and the ability to predict difficult intubation in general (lean) and obese patients

Tests	Definition	Cut-off point
1. Malformation of teeth	Buck,[20] protruded or missing teeth central teeth in the upper jaw.[22]	--
2. Inter-incisor gap (IIG)	The maximal distance between the upper and lower incisors, measured while patients sat in the neutral position.[23]	1. ≤ 3.5 cm (Thai) (Sn39, Sp 69, PPV 15, NPV 89)[24] 2. ≤ 4 cm (West African) (Sn30.8, Sp 97.3, PPV 28.6)[23] 3. ≤ 4.5 cm (Iran) (AUC 0.72, Sn 68.4, Sp 77, PPV 13.5, NPV 97.8)[25]
3. Upper Lip Bite (ULBT)	Class I: lower incisors could bite the upper lip above the vermillion line. Class II: lower incisors could bite the upper lip below the vermillion line. Class III: lower incisors could not bite the upper lip[25]	Class III (Iran) (AUC 0.85, Sn 78.9, Sp 91.9, PPV 33.3, NPV 98.8)[25]

4. Mandibular protrusion test	The ability to slide the lower incisors in front of the upper ones Class A: the lower teeth might be placed in front of the top teeth Class B: the lower teeth might be placed in line with the top teeth Class C: the lower teeth could not reach the top teeth[26]	Class C
5. Modified Mallampati test (MMT)	The patients sat upright with the head in the neutral position. They were asked to open their mouth as wide as possible, protruded their tongue to a maximum, and without phonation. Class I: the soft palate, fauces, uvula and pillars could be seen Class II: the soft palate, fauces and uvula could be seen Class III: if only the soft palate and base of the uvula could be seen Class IV: if the soft palate was not visible[15]	Class III, IV (Thai) (Sn41.7, Sp 95.5, PPV 23.1, NPV 98)[27]
6. Hyomental distance (HM)	The distance just above hyoid bone to the tip to the anterior-most part of the mentum in the neutral position[28]	--
7. Neck circumference (NC)	The level of the cricoid cartilage, perpendicular to the long axis of the neck[19]	NC > 43 cm. (Obese in France) (Sn 92, Sp 84, PPV 37, NPV 99)[5]

8. Length of neck	The length from the external occipital protuberance to the vertebra prominens as well as the circumference at the level of the cricoid cartilage anteriorly and spinous process of the sixth cervical vertebra posteriorly.[20]	--
9. Range of motion (ROM) of neck	1. Sagittal flexion, the subjects were required to make a "double chin" (suboccipital flexion) then flex fully forward 2. Sagittal extension, nodding the head back and then fully extending. 3. Lateral flexion, the subjects fixed their gaze on a set point directly ahead and were observed whilst laterally flexing both to the right and then to the left. 4. Lateral rotation, the subject looks to the right and then left whilst holding a horizontal gaze parallel to the floor.[29]	1. Limited neck movement= inability to extend and flex the neck to a range around 90 degree.[5] 2. From Wilson score: Level 0 = > 90° Level 1 = about 90° Level 2 = < 90°[20]
10. Thyromental distance (TM)	The straight line between the thyroid notch and the bony point of mentum with the head fully extended, measured in supine position with the head fully extend and with the mouth close.[25,27]	1. TMD < 6 cm (Thai) (Sn 23.3, Sp 86.1, PPV 16.5, NPV 97.4)[27] 2. TMD ≤ 6.5 cm. (Iran) (AUC 0.78, Sn 73.6, Sp 82.2, PPV 17.9, NPV 98.3)[25] 3. TMD ≤ 6.5 cm. (Thai) (Sn 52, Sp 71, PPV 21, NPV 91)[24]

11. Sternomental distance (SM)	1. The straight distance between the upper border of the manubrium sterni and the bony point of the mentum, measured in supine position with the head fully extend and with the mouth close.[25] 2. The distance is measured in the seated position with the head fully extended on the neck and with the mouth close.[23]	1. SMD ≤ 13.5 cm. (Iran) (AUC 0.77, Sn 84.2, Sp 70.6, PPV 13.1, NPV 98.8)[25] 2. SMD ≤ 13.5 cm. (West African) (Sn 0, Sp 100, PPV 0)[23]

Note: Sn = sensitivity; Sp = specificity, PPV= positive predictive value; NPV = negative predictive value; AUC = area under the curve.

Table 2: Studies of difficult intubation in obese patients

Study	BMI obese subjects (kg/m^2)	Number of obese patients	Incidence of difficult intubation in obese patients (n, %) (criteria)	Variables and tests	Risk factors
Voyagis et al,[30] 1998	≥ 30	99	20 (20.2) (Mallampati class III)	Oropharyngeal structures by passive and active pulling out the tongue	Disproportionately large base of tongue
Brodsky et al,[31] 2002	> 40	100	12 (12) (only epiglottis was visible)	Age, sleep apnea IIG (cm) MMT SM (cm) TM (cm) NC (cm)	NC at the level of thyroid cartilage
Juvin et al,[16] 2003	≥ 35	129	20 (15.5) (IDS ≥ 5)	Age, sex, BMI, snoring, OSA, DM MMT ROM (from Wilson score) IIG ± buck teeth ± mandibular recession Tooth missing	MMT class III, IV OR 12.51, 95%CI 2.01-77.81) Sn 85% Sp 62% PPV 29% NPV 96%
Ezri et al,[32] 2003	>35	200	24 (12) (CL III, IV)	Age, sex, OSA Abnormal upper teeth IIG Mandibular protrusion test TM Limit neck movement MMT	Older age 1.02 (1.006–1.04) Male 1.89 (1.09–3.26) Pathological TMJ 21.5 (3.36–137.9)

					History of OSA 10.6 (4.7–19.8) Higher MMT grade 4.2 (2.8–6.4) obese and abnormal teeth 11.4 (1.06–123)
Mashour et al,[9] 2008	≥40	376	… (5) (CL III, IV)	MMT EMS (The extended Mallampati score) TM DM OSA Snoring Thick neck Limited cervical spine and jaw movement Limited mouth opening	DM MMT III, IV (patient sitting upright, head neutral, tongue protruded no phonation) EMS III, IV (patient sitting, craniocervical junction extended, mouth open fully, tongue protruded, no phonation, and the examiner eye-to-eye)
Gonzalez et al,[5] 2008	≥ 30	70	10 (14.3) IDS > 5	BMI NC MMT class >3	NC > 43 cm. MMT class >3 TM

				TM SM Wilson score >2 El-Ganzouri >4	BMI
Neligan et al,[10] 2009	≥ 35	180	(8.3) (CL III, IV)	BMI, Sex OSA NC	Male gender MMT class III, IV
Hagburg et al,[17] 2008	>34	283	Need fiberoptic intubation	BMI, sex, age MMT History of Gastro-esophageal reflux, peptic ulcer, hiatal, hernia, OSA	MMT class III, IV
Kim et al,[19] 2011	≥ 27.5	123	(13.8) (IDS ≥ 5)	Age, BMI, sex, History of difficult , intubation, MMT IIG, NC, TM, SM, Wilson score	Wilson score MMT class III, IV NC/ TM
Iyer et al,[33] 2011		267		OSA, sex MMT, TM NC ≥ 44 cm	Severe OSA NC ≥ 44 cm

Note: OR= odds ratio; OSA = obstructive sleep apnea; DM = diabetic mellitus; TMJ = temporomandibular joint; IDS = Intubating Difficulty Scale.

Table 3: Wilson Risk Sum Score[20]

Factors	Level	
Weight	0 1 2	< 90 kg 90 -110 kg >110 kg
Head and neck movement	0 1 2	Above 90° About 90° (i.e. ± 10°) Below 90°
Jaw movement	0 1 2	IG ≥ 5 cm or SLux > 0 IG < 5 cm or SLux = 0 IG < 5 cm or SLux < 0
Receding mandible*	0 1 2	Normal Moderate Severe
Buck teeth* (long upper incisors)	0 1 2	Normal Moderate Severe

Note: IG = inter-incisor gap; SLux = subluxation, maximal forward protrusion of the lower incisors beyond the upper incisors.

*The authors estimated the severity of receding mandible and long upper incisors (buck teeth) by using subjective three-point scale (0 = normal; 1 = moderate; 2 = severe). The reliability of the scales was confirmed with a series of photographs. The chance that a second colleague would agree with the assessment of a first colleague was at least in their study.

Table 4: Naguib model[13]

Predictive model = 0.2262 – 0.4621 X thyromental distance + 2.5516 X Mallampati score – 1.1461X IG + 0.0433 X height

Table 5: Simplified Score Model by Arné et al.[21]

Factor	Score
Previous knowledge of difficult intubation No Yes	 0 10
Diseases associated with difficult intubation No Yes	 0 5
Clinical symptoms of airway pathology No Yes	 0 3
IG and SLux IG ≥ 5 cm or SLux > 0 IG < 5- 3.5 cm and SLux = 0 IG < 3.5 cm or SLux < 0	 0 3 13
Thyromental distance ≥ 6.5 cm < 6.5 cm	 0 4
Maximum range of head and neck movement More than 100° About 90° (± 10°) Less than 80°	 0 2 5
Mallampati score Class I Class 2 Class 3 Class 4	 0 2 6 8
Total possible	48

CHAPTER III

RESEARCH METHODOLOGY

3.1 Research question

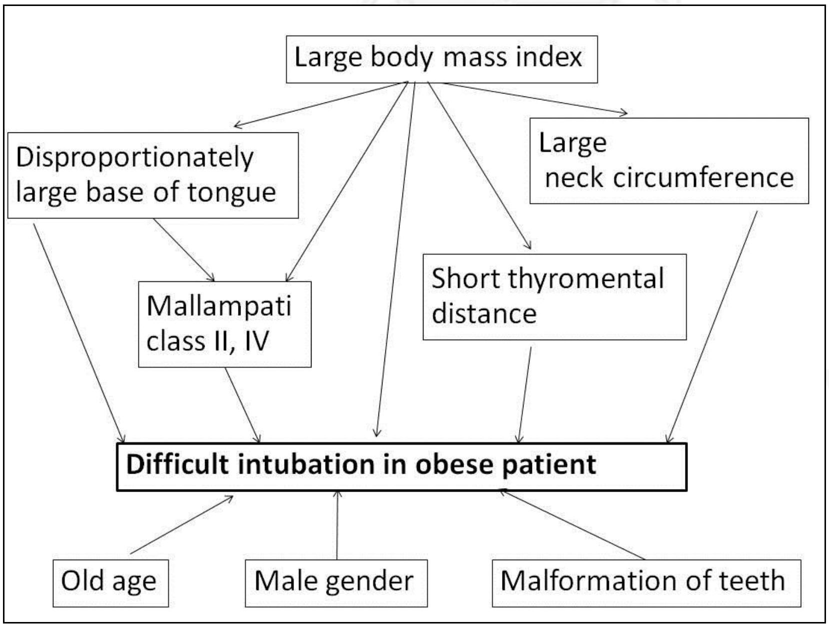
What types of bedside physical examination could predict difficult intubation in Thai obese patients?

3.2 Research Objectives

1. To set up a practical new predictive model
2. To validate the predictive model with a separate set of patients

3.3 Figure 1: Conceptual framework

All risk factors of difficult intubation in obese patients from literature[5,9,10,30,31,32] were added in this conceptual framework.



3.4 Research design

Prospective observation multicenter study

3.5 Population and sample

Target population: Adult obese patients who underwent elective surgery under general anesthesia with tracheal intubation.

Study population: Adult obese patients at Siriraj hospital, Suratthani hospital, Taksin hospital, and Ratchaburi hospital who underwent surgery under general anesthesia with tracheal intubation.

Table 6: Participating institutions

Hospital	Co-investigator
Siriraj	Asst. Prof. Arunotai Siriussawakul
Suratthani	Dr. Aticha Suwanpratheep
Taksin	Dr. Subongkot Kueprakone
Ratchaburi	Dr. Suthasinee Samankatiwat

Patient selection:

Inclusion criteria

1. Adult (age > 18)
2. Body mass index (BMI = weight/ height^2) of $\geq$30 kg/ m^2.
3. Patients undergoing general anaesthesia with tracheal intubation ± regional anesthesia.
4. Elective surgery

Exclusion criteria

Patients with known problematic airway conditions were not the scope of this present study. Airway difficulty was recognized in patients with anatomic and physiologic changes such as patients with malformation features of head and neck from congenital anomalies or trauma, pregnancy[34] or patients with previous history of difficult airway management. All of undoubtedly conditions of difficult airway management almost always alert anesthetic personnel to concentrate on methods of securing the airway and seeking for safety management before induction of anesthesia. Therefore, the exclusion criteria in our study were

1. Upper airway pathology or obvious malformations of upper airway (i.e. maxillofacial fractures, tumors)
2. Cervical spine fracture
3. Pregnancy
4. Patient with a history of difficult intubation or failed intubation, and needed alternative intubation techniques.
5. Patients who were initially managed with alternative airways such as fiberoptic intubation, video-laryngoscope or laryngeal mask airway.

3.6 Methods

We specified the requirements for a predictive tool as the following:

1. Selected predictive factors came from physical examination, and the tests must easy for assessment at bedside or at preoperative clinic.
2. Only a tape measurement and a ruler were required for the assessment, and no complex apparatus should be needed.
3. Final score could be calculated easily, and the cut-off point could discriminate high risk patients from low risk patients.
4. User friendly

<u>Training research assistants</u>

Before conducting research, we set a meeting for training research assistants. We invited 2 research assistants and one anesthesiologist from each site. The objectives of the meeting were

1. Explained operational definition
2. Demonstrated methods of measurement by the principle investigator.
3. Practiced measure: we invited 5 obese volunteers (BMI $\geq$30 kg/ m^2) to the meeting. All research assistances performed measurement.
4. A series of photographs were used to for checking inter-observer reliability

5. Data from measurement were collected for checking inter-observer reliability between principle investigator and research assistances before starting research with enrolled patients.

Preoperative assessment

Airway examinations which were potential factors were assessed by research assistants on the day before surgery for in-patients or at preoperative clinic or preoperative area for ambulatory or out-patients by trained the investigators who were not involved in the operative care of the patients. Demographic data, underlying diseases and history of airway management were recorded in a case record form.

Intraoperative management

- All tracheal intubations were performed by the anesthetists who had more than 2 years full-time of experience and they were blinded to the detail of the patient assessment.
- The anesthesiologists who performed intubation were not restricted by a study protocol and they were free to choose the laryngoscopic position and intubating technique to achieve optimal visualization in each particular patient.
- The patient was positioned with a pillow under the head with the neck extended as appropriate.
- Each patient was monitored routinely with an electrocardiogram, pulse oximetry, non-invasive arterial pressure and capnograph
- Patients were considered to receive preoxygenation with breath 100% oxygen through a facemask for more than 3 minutes
- Anesthesia was conducted with sodium thiopental (5-7 mg /kg) or propofol 1.5 – 2.5 mg/ kg, and intubating dose of muscle relaxants.
- Any laryngoscope blade was used for the first laryngoscopy in each case.
- If SpO2 decreased to 90% for more than 3 minutes or 85% once during the intubation period, the event was recorded as a hypoxic episode.

3.7 Operational definition

Definition of 11 tests which were examined by research assistances

1. Body mass index was calculated from weight (kg) / height^2(m)
2. Malformation of teeth in the upper jaw: buck, protrude or missing teeth. The malformation of teeth was estimated on a subjective two scale, yes or no.

Figure 2, 3: "Yes" = there were some kinds of malformation of teeth in the upper jaw which could impede the position of laryngoscope blade during intubation.

Figure 4: “No” = no malformation of teeth in the upper jaw.

Figure 5: Inter-incisor gap means the maximal distance between the upper and lower incisors or gingival, measured while patients sat in the neutral position

3. Upper Lip Bite test

Figure 6: Class I: lower incisors could bite the upper lip above the vermillion line.

Figure 7: Class II: lower incisors could bite the upper lip below the vermillion line.

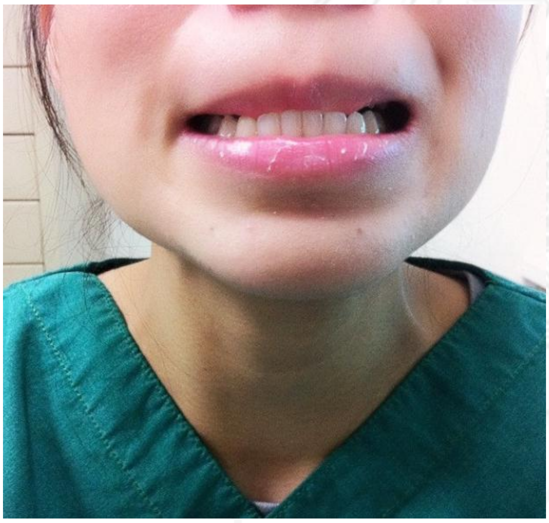


Figure 8: Class III: lower incisors could not bite the upper lip

Figure 9: Mallampati classification: the patients sat upright with the head in the neutral position. They were asked to open their mouth as wide as possible, protrude their tongue to a maximum, and without phonation.

Class I: the soft palate, fauces, uvula and pillars could be seen.

Class II: the soft palate, fauces and uvula could be seen.

Class III: if only the soft palate and base of the uvula could be seen.

Class IV: if the soft palate was not visible.

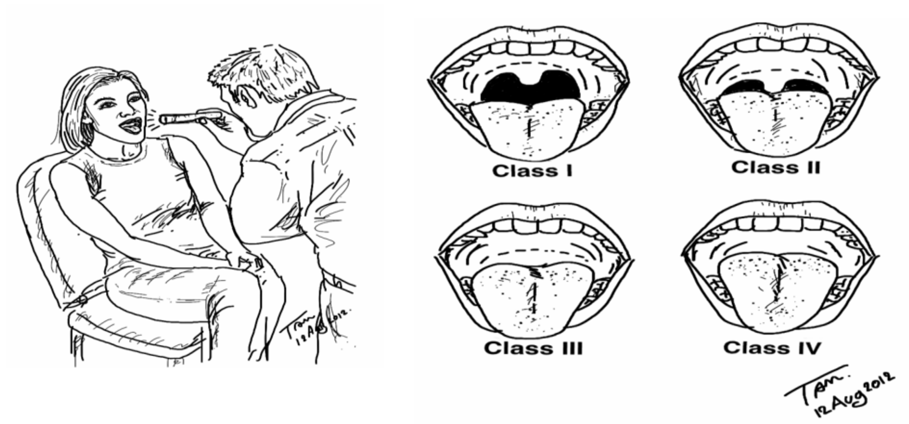
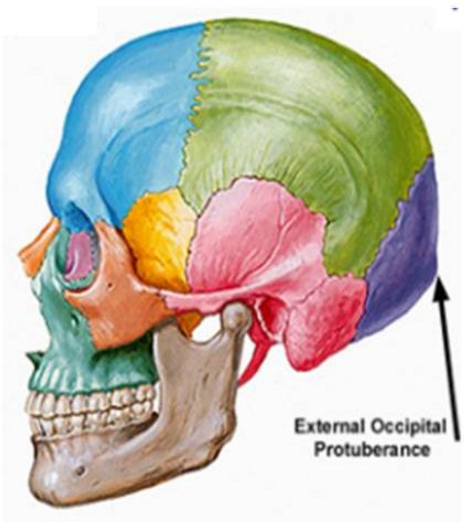


Figure 10: Neck circumference was measured at the level of the cricoid cartilage, perpendicular to the long axis of the neck

Figure 11: Length of neck means the length from the external occipital protuberance to the vertebra prominens of spinous process of the seventh cervical vertebra posteriorly.



4. Range of motion of neck

Figure 12: Sagittal flexion, the subjects were required to make a ''double chin'' (suboccipital flexion) then flex fully forward

"**Yes**" means a subject could flex fully forward.

"**No**" means a subject could not flex fully forward

Figure13: Sagittal extension, nodding the head back and then fully extending.

"**Yes**" means a subject could extend fully backward.

"**No**" means a subject could not extend fully backward.

Figure 14: Hyomental distance means the distance just above hyoid bone to the tip to the anterior-most part of the mentum in the neutral position.

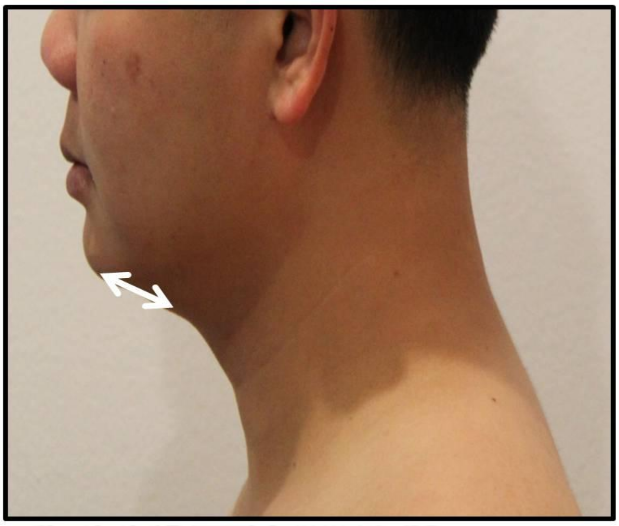


Figure 15: Thyromental distance means the straight line between the thyroid notch and the bony point of mentum with the head fully extended, measured in supine position with the head fully extend and with the mouth close.

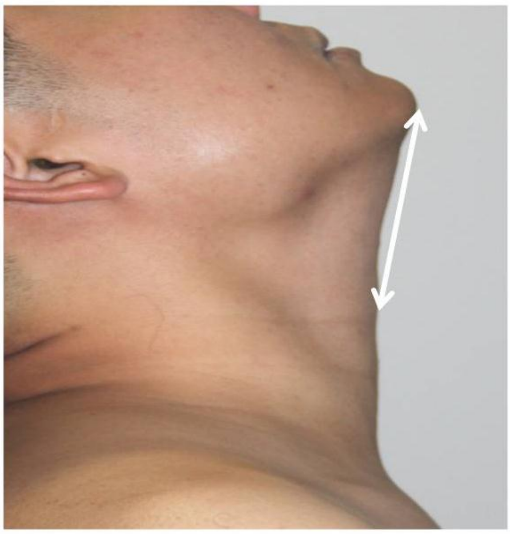
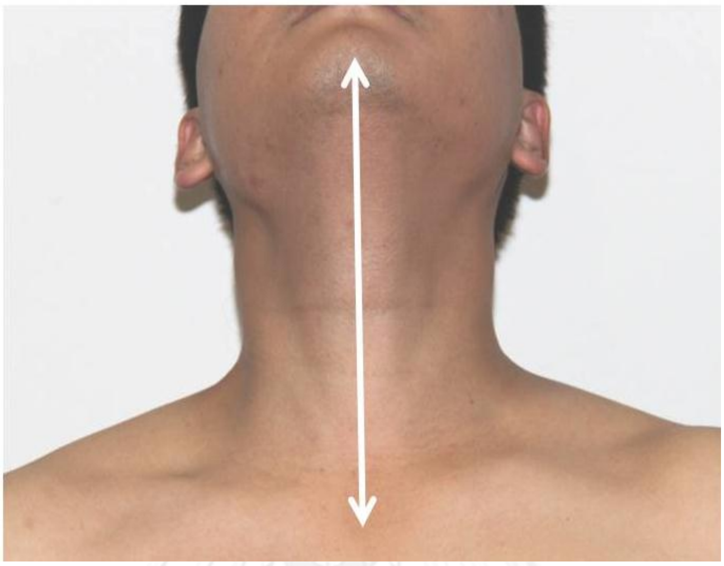


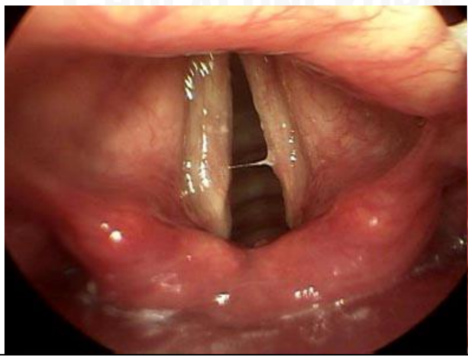
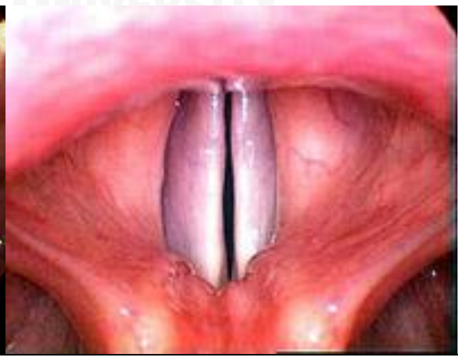
Figure 16: Sternomental distance means the distance between the upper border of the manubrium sterni and the bony point of the mentum, measured in the seated position with the head fully extended on the neck and with the mouth close.



3.8 Definition of the outcome criteria

The intubation difficulty scale (IDS) score was used in this study in order to avoid discrepancy of the term “difficult intubation”. This score was composed of seven variables. Those chosen factors (demonstrated in Table 7) were identified in the literature as associated with difficult intubation. N1, which was the number of attempt, was the parameter most frequently described as being associated with difficult intubation. Grading of laryngoscopic view by Cormack-Lehane (N4) was also a part of IDS score. The scheme of laryngoscopic view has become a standard measurement of glottic views, and facilitates communication regarding the condition of intubation difficulty between researchers and clinicians. The IDS score could be used to compare difficulty of intubation under varying circumstances by summation of seven variables or isolating variables of interest. This score was already utilized to compare between obese and non-obese patients.[5] Adnet et al, validated the IDS score with the subjective difficulty (easy, somewhat difficult, and difficult) and a Visual Analog Scale (VAS) in operating room series and pre-hospital series. In combining both series, 100% of intubations in which The IDS > 5 were associated with a subjective perception of being somewhat difficult or difficult on the part of the operators. Among intubations with an IDS $\leq$ 5, 77% were subjectively considered as easy intubations. As a result, the cut-off point for difficult intubation was IDS > 5. The sum score of 0 referred to easy or ideal intubation, i.e., one performed without effort, on the first attempt, practiced by one operator, used one technique, with no impediment of tube passage. The score value increased when an additional attempt was added and the score of ∞ referred to impossible intubation.[35] We defined the IDS scores > 0 as the troublesome intubation which meant that there were some degrees of problematic while performing endotracheal intubation.

Table 7: Definition of seven variables included in the intubation difficulty scale (IDS) score.[35]

Item	Definition
N1	The number of attempts of endotracheal intubation
N2	The number of operators who performed endotracheal intubation
N3	The number of alternative intubation techniques used if the first attempt was not success
N4	Laryngoscopic view as defined by Cormack and Lehane grade 1, the vocal cords were completely visible, N4 = 0 grade 2, only the arytenoids were visible, N4 = 1 grade 3, only the epiglottis was visible N4 = 2 grade 4, the epiglottis was not visible, N4 = 3 
N5	The lifting force applied during laryngoscopy (0= little effort was necessary, 1= if subjectively increased lifting force was necessary)
N6	The necessity to apply external laryngeal pressure for optimized glottic exposure 0 = no external pressure or only the Sellick maneuver was applied, 1= external laryngeal pressure was used
N7	Position of the vocal cords at intubation (0= abduction, 1= adduction or presenting an impediment to tube passage) 

3.9 Data analysis

The sample size estimation was based on the current recommendation among statisticians for multiple logistic regression analysis, i.e., that the number of obese subjects with IDS >5 was around five to ten times of the number of risk factors of interest.[36] Since there were about four risk factors (i.e., upper lip bite test, Modified Mallampati tests, inter-incisor gap and neck circumference) in the model, 40 obese subjects with IDS > 5 were required. Based on the previous incidence report of IDS > 5 of 15%[19] and the sample size was inflated by 15% due to unexpected incomplete data, thus, a sample of 280 subjects was recruited.

Inter-rater reliability of measurements between primary investigator (PI) and all research assistances were assessed using intraclass correlation (ICC) and percentage of observed agreement for quantitative and qualitative variables respectively. The strength of agreement index≥ 0.7 was adopted (< 0.00 = poor concordance; 0.00–0.20 = slight concordance; 0.21–0.40 = fair concordance; 0.41– 0.60 = moderate concordance; 0.61– 0.80 = substantial concordance; and 0.81–1.00 = almost perfect concordance).

Baseline demographic data were summarized according to types of variable e.g., mean and standard deviation (SD) for quantitative variable, number and percentage for qualitative variable. Proportions of having difficult intubation (IDS > 5) and troublesome intubation (IDS > 0) were reported.

Raw IDS scores from all 280 subjects were also analyzed. Due to positive skewness of IDS scores, Spearman’s rank correlation, Mann-Whitney U test and Kruskal Wallis test were used to determine factors associated with IDS score.

To develop and validate a model for troublesome intubation (IDS > 0), 280 subjects were divided into two data sets i.e., development set and validation set. That is, 200 subjects from Siriraj Hospital were used to develop a model and the remaining 80 subjects from other sites for validating a model. Model developing process started from univariable analysis to determine factors associated with troublesome intubation e.g., 2-sample t-test, Chi-square test, crude odds ratio (OR) and 95% CI. Variables with univariable p-value < 0.2 or variables of interest were then entered into a multiple logistic regression model. To get a parsimonious logistic regression model, only independent variables with p value < 0.05 were kept in the final model. A risk score ($z = b_0 + b_1x_1 + b_2x_2 + \ldots + b_px_p$) was then developed based on regression coefficients (b) from the final logistic regression model. Results were reported as adjusted OR and 95% CI. Probability of having troublesome intubation in each subject was then computed from a risk score. Receiver operating characteristic (ROC) curve was then applied to determine sensitivity, specificity for each cut point for probability of having troublesome intubation. Area under ROC curve was also reported to assess overall discrimination ability of the logistic regression model.

Multicollinearity among independent variables in the model was tested using variance inflation factor (VIF). Goodness-of-fit of the final model was assessed using Hosmer-Lemeshow chi-square test which tested the agreement between predicted probabilities based on the model and the actual observed probabilities.

Once the final model was developed, it was assessed in the separate validation set of eighty patients. The final logistic regression model based on 200 subjects was applied to this set of 80 subjects. Using the cut point for predicted probability of difficult intubation obtained earlier from 200 subjects, discrimination ability of the model among 80 subjects was assessed via sensitivity, specificity and predictive values.

Statistical analysis was conducted using SPSS version 18 Inc., Chicago, IL, USA.

CHAPTER IV

RESULTS

The study was approved by Siriraj Institution Review Board, and ethic committee from Suratthani Hospital, Taksin Hospital and Ratchaburi Hospital.

Inter-observer reliability

The inter-observer reliability between the principle investigator (PI) and two assistants at Siriraj Hospital was presented in Table 8. Prior to the initiation of the study, research assistants were trained for three sessions with five obese volunteers until almost perfect results were obtained. Most measurements showed either substantial or almost perfect reliability, but some measurements, such as the measurement of the length of the neck, the hyomental distance and the thyromental distance, demonstrated slight to fair reliability during the first and second training sessions. (Table 8) As for a test using a set of photographs, both research assistants did perfect results in every session. (Table 9) The similar process of the reliability tests were performed at Suratthani Hospital, Taksin Hospital and Ratchaburi Hospital. The final results of inter-observer reliability between the principle investigator and two nurse anesthetists from each site were greater than 0.7 before data collection. (Table 10)

Table 8: Agreement in airway examination between PI and two assistants (A1, A2) at Siriraj Hospital

Variables	ICC or percentage observer agreement					
	Session 1		Session 2		Session 3	
	PI: A1	PI: A2	PI: A1	PI: A2	PI: A1	PI: A2
Inter-incisor gap (cm.)	0.99	0.83	0.71	0.94	0.99	0.99
Neck circumference (cm.)	0.90	0.91	0.97	0.97	0.99	0.99
Length of neck (cm.)	-0.85	0.31	0.41	0.12	0.93	0.87
Hyomental distance (cm.)	0.37	0.50	0.60	0.51	0.93	0.99
Thyromental distance (cm.)	0.41	0.30	0.25	0.13	0.72	0.95
Sternomental distance (cm.)	0.85	0.42	0.97	0.78	0.99	0.98
Malformation of teeth	100	100	100	100	100	100
Mallampati classification	0	80	80	60	100	100
Upper Lip Bite test	80	80	80	80	100	100
Range of motion of neck						
Flexion	100	100	100	100	100	100
Extension	100	100	100	100	100	100

Note: ICC = intraclass correlation, cm. = centimeters.

Table 9: Agreement in airway examination of a series of photographs between PI and two assistances (A1, A2) at Siriraj Hospital.

Variables	Accuracy (%)					
	Session 1		Session 2		Session 3	
	PI: A1	PI: A2	PI: A1	PI: A2	PI: A1	PI: A2
Malformation of teeth	100	100	100	100	100	100
Mallampati classification	100	100	100	100	100	100
Upper Lip Bite test	100	100	100	100	100	100
Range of motion of neck						
Flexion	100	100	100	100	100	100
Extension	100	100	100	100	100	100

Table 10: The final agreement in airway examination between PI and research assistants at three participating sites.

Variables	ICC or percentage observer agreement					
	Surathani Hospital (SU)		Taksin Hospital (TS)		Ratchaburi Hospital (RA)	
	PI: SU 1	PI: SU 2	PI: TS1	PI: TS2	PI: RA1	PI: RA2
Inter-incisor gap (cm.)	0.70	0.77	0.71	0.84	0.70	0.70
Neck circumference (cm.)	0.82	0.97	0.97	0.94	0.89	0.99
Length of neck (cm.)	0.89	0.70	0.70	0.70	0.72	0.75
Hyomental distance (cm.)	0.72	0.75	0.81	0.77	0.71	0.73
Thyromental distance (cm.)	0.85	0.91	0.82	0.72	0.72	0.75
Sternomental distance (cm.)	0.85	0.98	0.77	0.78	0.79	0.78
Malformation of teeth	100	100	100	100	100	100
Mallampati classification	80	80	80	80	80	80
Upper Lip Bite test	80	80	80	80	80	80
Range of motion of neck						
Flexion	100	100	100	100	100	100
Extension	100	100	100	100	100	100

Note: ICC = intraclass correlation, cm. = centimeters.

<u>Demographic data</u>

Overall, data of 280 adult patients who underwent elective surgery from May 1, 2013 to February 28, 2014 were obtained. Data of two hundred cases were collected from Siriraj Hospital, forty six cases from Suratthani Hospital, twenty nine cases from Taksin Hospital and five cases from Ratchaburi Hospital. The mean age of patients was 49.4 years, with 25% of patients being male and the remaining 75% being female. The average body mass index was 34.6 ± 5.0 kg/m^2 (range 30-68.4 kg/m^2). Around two thirds of patients had at least one coexisting disease, and common diseases were hypertension, diabetic mellitus and dyslipidemia. Obstructive sleep apnea was diagnosed in fourteen patients. Surgical procedures and surgical areas were detailed in Table 11. Almost patients got IDS scores < 5. There were only three patients got IDS score >5. Patient No.1 was a 32 years old woman with BMI 36.2 kg/m^2. She was diagnosed with endometriosis and underwent explore laparotomy at Siriraj Hospital. Patient No.2 was a 36 years old man with BMI 32.3 kg/m^2. He was diagnosed with severe obstructive sleep apnea and underwent tonsillectomy with uvulopalatoplasty flap at Suratthani Hospital. Conventional endotracheal intubation was impossible, and fiberoptic intubation was performed. Patient No.3 was a 42 years old woman with BMI 36.2 kg/m^2. She was also diagnosed with severe obstructive sleep apnea and underwent uvulopalatopharyngoplasty (UPPP) at Suratthani Hospital. Their IDS scores were 6, 11, and 12, respectively. Data in Table 12 also demonstrated demographic data of all patients participated in this study. Data were separated to two set, developing set (n =200) and validating set (n = 80).

Table 11: Data of patients with IDS 0, IDS 1-5 and three patients with IDS > 5.

Variables	Mean ± SD or number (%)				
	Patients with IDS 0 (n = 135)	Patients with IDS 1-5 (n = 142)	Patient 1: IDS 6	Patient 2: IDS 11	Patient 3: IDS 12
Body mass index (kg/m^2)	34.1 ± 3.7	35.1 ± 6.1	32	36	36.2
Inter-incisor gap (cm.)	5.2 ± 0.7	5.0 ± 0.7	5	4.6	4.5
Neck circumference (cm.)	38.0 ± 3.1	39.6 ± 3.8	39.2	45.4	37.2
Length of neck (cm.)	10.9 ± 1.8	11.2 ± 1.6	12	9	10.3
Hyomental distance (cm.)	5.0 ± 0.8	4.9 ± 0.8	6.5	6	5.8
Thyromental distance (cm.)	10.0 ± 1.4	9.8 ± 1.5	11.5	10.5	10.4
Sternomental distance (cm.)	16.4 ± 2.3	16.3 ± 2.3	18	16	17.2
Malformation of teeth					
Yes	24 (17.8)	31 (21.8)			
No	111 (82.2)	111 (78.2)	√	√	√
Mallampati classification					
I	44 (32.6)	25 (17.6)		√	
II	47 (34.8)	50 (35.2)			√
III	20 (14.8)	47 (33.1)	√		
IV	24 (17.8)	20 (14.1)			
Upper Lip Bite test					
I	89 (65.9)	86 (60.6)	√	√	
II	40 (29.6)	42 (29.6)			√
III	6 (4.4)	14 (9.9)			
Limitation of range of motion of neck					
Flexion					
Limit	0	0			
Not limit	135 (100)	142 (100)	√	√	√
Extension					
Limit	5 (3.7)	8 (5.6)		√	
Not limit	130 (96.3)	134 (94.4)	√		√

Table 12: Demographic data of 280 obese patients

Variables	Mean ± SD or number (%)		
	Development set (n = 200)	Validation set (n=80)	Total (n=280)
Age (year)	51.1 ± 14.6	45.2 ± 13.6	49.4 ± 14.6
Gender			
Male	58 (29)	12 (15.0)	70 (25)
Female	142 (71)	68 (85.0)	210 (75)
Body mass index (kg/m^2)	34.7 ± 5.3	34.4 ± 4.2	34.6 ± 5.0
ASA Classification			
II	178 (89)	60 (75)	238 (85)
III	22 (11)	20 (25)	42 (15)
Specialties			
Head neck breast surgery	42 (21.0)	2 (2.5)	44 (15.7)
General surgery	37 (18.5)	30 (37.5)	67 (23.9)
Orthopedics	34 (17.0)	4 (5.0)	38 (13.6)
Otolaryngology	27 (13.5)	9 (11.3)	36 (12.9)
Gynecology	17 (8.5)	26 (32.5)	43 (15.4)
Neurology	11 (5.5)	1 (1.3)	12 (4.3)
Others	31 (16)	8 (10.)	40 (14.3)
Surgical area			
Head and neck	66 (33)	11 (13.8)	77 (27.5)
Abdomen	46 (23)	48 (60)	94 (33.6)
Breast	32 (16)	11 (13.8)	43 (15.4)
Extremities and spine	31 (15.5)	4 (5)	35 (12.5)
Other	25 (12.5)	6 (7.4)	31 (11.0)

We observed all intubations during the period of evaluation.

Conventional endotracheal intubation performed by a certified anesthesiologist or a certified nurse anesthetist who had two or more years of experience in anesthesiology. Anesthesia was induced by administering propofol, thiopental or etomidate. Intubations were performed after pharmacological paralyzed, being confirmed by clinical observation of muscle relaxation or by a value of train of four stimulation of adductor pollicis muscle equal to zero. Most direct laryngoscopies (76.1%) were successful, using a McIntosh laryngoscope blade number 3. Other laryngoscopies were possible by using a McIntosh laryngoscope blade number 4 (17.5%), a McCoy laryngoscope blade (5%) and a Miller blade (1.4%).

The distribution of IDS scores was presented in Table 13. Ideal intubation, with an IDS value = 0, represents 48.2% of all intubations. Overall, some degree of problematic intubation occurred in 51.8% of all obese patients. The percentage of intubations with slight difficulty, i.e., with an IDS value of 1-5, was 50.7% (142 out of 280). Moderate to major difficulty of intubation (IDS > 5) occurred in only three cases. No failed intubation was reported in this study.

Table 13: The number of patients classified by the intubation difficulty scale (IDS) scores

Degree of difficulty	IDS score	Number (%)		
		Development set (n = 200)	Validation set (n=80)	Total (n=280)
Easy	0	95 (47.5)	40 (50.0)	135 (48.2)
Slight difficulty	1	62 (31)	11 (13.8)	73 (26.1)
	2	21 (10.5)	10 (12.5)	31 (11.1)
	3	16 (8)	5 (6.3)	21 (7.5)
	4	3 (1.5)	11 (13.8)	14 (5.0)
	5	2 (1)	1 (1.3)	3 (1.1)
Moderate to major difficulty	6	-	1 (1.3)	1 (0.4)
	11	-	1 (1.3)	1 (0.4)
	12	1 (0.5)	-	1 (0.4)

<u>Factors associated with IDS scores</u>

All airway examinations were analyzed to identify which factors were related to patients with troublesome intubation. We demonstrated ten airway assessment tests reviewed from literature in Table 14. Association of possible factors related to difficult intubation and raw IDS scores revealed that none of factors in this presented data were presented in Table 14. The results revealed that no association of any factors and raw IDS scores.

Table 14: Association between types of physical examinations and IDS scores.

Variables	n	Median (Min, Max)	Correlation (r)	p-value
Body mass index (kg/m2)	280	33.2 (30.0, 68.4)	0.059	0.326
Inter-incisor gap (cm)	280	5 (3, 7.8)	-0.057	0.341
Neck circumference (cm)	280	38 (31, 50)	0.187	0.002
Length of neck (cm)	280	11 (5, 17.5)	0.097	0.105
Hyomental distance (cm)	280	5 (2.5, 7.3)	0.030	0.620
Thyromental distance (cm)	280	10 (7, 13.5)	-0.014	0.816
Sternomental distance (cm)	280	16 (10.5, 24.2)	-0.018	0.761
Malformation of teeth				
No	225	-	-	0.261
Yes	55	-	-	
Mallampati classification				
I	70	-	-	<0.001
II	98	-	-	
III	68	-	-	
IV	44	-	-	
Upper lip bite test				
I	177	-	-	0.065
II	83	-	-	
III	20	-	-	
Limitation of range of motion of neck				
Flexion				
Not limit	280	-	-	-
Limit	0	-	-	
Extension				
Not limit	266	-	-	0.180
Limit	14	-	-	

Note: r = Spearman rank correlation; p value came from Mann Whitney U test and Kruskal-Wallis test.

<u>Development and validation of model for troublesome intubation</u>

Due to only three patients with IDS >5, IDS score was then categorized using cut point of zero (Ideal intubation, IDS score = 0 vs. troublesome intubation, IDS > 0. Logistic regression model for troublesome intubation based on 200 patients from Siriraj Hospital was then developed. Eleven airway examinations were analyzed to identify which factors were related to troublesome intubation. Based upon a univariable analysis, three factors were found to be statistically significant: the inter-incisor gap, the neck circumference (NC) and the modified Mallampati (MMT) test (Table 15). However, a total of five independent variables of interest i.e., inter-incisor gap, NC, length of neck, upper lip bite test (I, II, III) and modified MMT (I, II, III, IV) were entered into the first logistic regression model (Table 16, Model 1). To simplify a model, variables that were not related to troublesome intubation (p-value > 0.05) were excluded i.e., length of neck and upper lip bite test. Model 2 which was the final model then comprised only three independent variables. It revealed that patients with bigger neck circumference had a higher risk of troublesome intubation with adjusted OR of 1.15 for one centimeter increment in NC or equivalently OR of 2.01 for five centimeters increment in NC. Decreased in one centimeter of inter-incisor gap increased the risk of troublesome intubation to 1.59 (95% CI: 1.03, 2.50). Regarding modified Mallampati test, class II and III had a higher risk of troublesome intubation compared to class I (adjusted OR of 2.20 and 3.68 respectively). The final logistic regression fit the data quite well with p-value from Hosmer-Lemeshow test of 0.254.

Table 15: Univariate analysis of factors associated with troublesome intubation (n=200)

Types	Patients with ideal intubation (n=95)	Patients with troublesome intubation(n=105)	p value	Crude OR (95%CI)
Inter-incisor gap (cm.)	5.13±0.73	4.96±0.72	0.108	0.73 (0.49,1.07)
Neck circumference (cm.)	37.87±3.18	39.69±4.05	0.001	1.15 (1.06,1.25)
Length of neck (cm.)	10.65±1.73	10.93±1.57	0.223	1.11 (0.94,1.32)
Hyomental distance (cm.)	4.82±0.72	4.80 ±0.81	0.826	0.96 (0.67,1.38)
Thyromental distance (cm.)	9.41±1.03	9.54±1.25	0.405	1.11 (0.87,1.42)
Sternomental distance (cm.)	15.9±2.23	16.04±2.33	0.565	1.04 (0.92,1.17)
Malformation of teeth	18 (50)	18 (50)	0.74	1.13 (0.55, 2.33)
Upper lip bite test			0.26	
I	56 (48.7)	59 (51.3)		1
II	35 (50)	35 (50)		0.95 (0.52, 1.72)
III	4 (26.7)	11 (73.3)		2.61 (0.79, 8.68)
Modified Mallampati test			0.006	
I	29 (64.4)	16 (35.6)		1
II	28 (45.9)	33 (54.1)		2.14 (0.97, 4.71)
III	15 (29.4)	36 (70.6)		4.35 (1.85, 10.25)
IV	23 (53.5)	20 (46.5)		1.58 (0.67, 3.71)
Limit neck movement				
Flexion	0	0		
Extension	3 (42.9)	4 (57.1)	0.802	2.61 (0.27, 5.57)

Table 16: Multiple logistic regression of factors associated with troublesome intubation (n=200)

Types	Model 1			Model 2 (Final model)		
	b	p value	Adj. OR (95%CI)	b	p value	Adj. OR (95% CI)
Inter-incisor gap (cm.)	-0.506	0.029	0.60 (0.38, 0.95)	-0.469	0.036	0.63 (0.40, 0.97)
Neck circumference (cm.)	0.143	0.001	1.15 (1.06, 1.26)	0.140	0.001	1.15 (1.06, 1.25)
Length of neck (cm.)	0.127	0.190	1.14 (0.94, 1.37)	-	-	-
Upper lip bite test						
II	-0.514	0.145	0.60 (0.30, 1.20)	-	-	-
III	0.410	0.534	1.51 (0.41, 5.48)			
Modified Mallampati test						
II	0.825	0.054	2.28 (0.99, 5.28)	0.786	0.060	2.20 (0.97, 4.98)
III	1.308	0.004	3.70 (1.50, 9.10)	1.304	0.004	3.68 (1.51, 8.98)
IV	0.209	0.650	1.23 (0.50, 3.05)	0.214	0.638	1.24 (0.51, 3.03)
Constant	-4.734	0.031	-	-3.567		
-2 Log-likelihood	245.68			249.85		
Hosmer-Lemeshow test	p = 0.343			p = 0.254		

Binary logistic regression equation for final model:

Z = -3.467 – 0.469*Incisor gap + 0.140*NC

+ 0.786 (if MMT = II) + 1.304 (if MMT = III) + 0.214 (if MMT = IV)

Modified MMT	Z
I	-3.467 – 0.469*Incisor gap + 0.140*NC
II	-3.467 – 0.469*Incisor gap + 0.140*NC + 0.786
III	-3.467 – 0.469*Incisor gap + 0.140*NC + 1.304
IV	-3.467 – 0.469*Incisor gap + 0.140*NC + 0.214

Probability of troublesome intubation $= \frac{e^Z}{1+e^Z}$

Since the equation of probability of troublesome intubation was not user friendly, Figure 17 could then help clinicians to find out the probability of troublesome intubation in each obese patient. The figure demonstrated that the probability of troublesome intubation increased when the risk score (Z) increased. When Z was 0, probability was 0.5. For example, if the calculated Z (risk score) was -2, then probability was 0.12.

Application of the logistic regression model

Data in Table 17 were demonstrated that how to use of the logistic regression model to obtain the predicted probability of troublesome intubation. Suppose the first subject had the inter-incisor gap of 5 cm, neck circumference of 37 cm and was in class I of MMT, his/her risk score (Z) would be -0.632. From Figure 17, when Z is -0.632, the probability of troublesome intubation is about 0.35.

Figure 17: Distribution of probability of troublesome intubation.

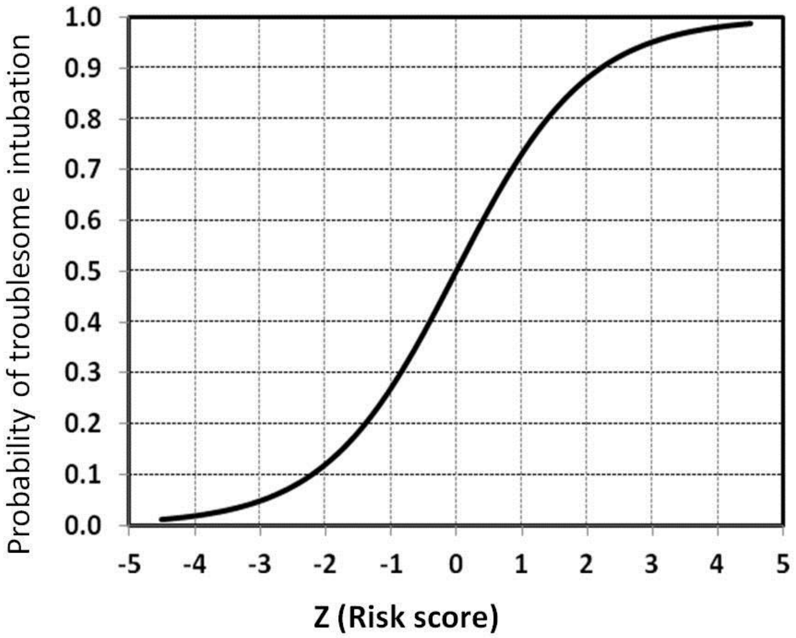


Table 17: Example of patients' data and calculation of the probability of troublesome intubation.

Subject	Incisor gap (cm)	NC (cm)	MMT	Z (risk score)	Probability of troublesome intubation (From Figure 17)
1	5	37	1	-3.467 – (0.469*5) + (0.14*37) = -0.632	0.35
2	4.2	38.5	2	-3.467 – (0.469*4.2) + (0.14*38.5) + 0.786 = -0.7392	0.66
3	3.3	40	3	-3.467 – (0.469*3.3) + (0.14*40) + 1.304 = 1.8893	0.88
4	2.8	45	4	-3.467 – (0.469*2.8) + (0.14*45) + 0.214 = 1.7338	0.85

To test the discrimination ability of the final logistic regression, ROC curve was applied to determine the effect of cut point for predicted probability of troublesome intubation on sensitivity and specificity (Figure 18). The area under ROC curve was 0.696. Table 18 demonstrated sensitivity, specificity, accuracy and predictive values for three selected cut points of probability of troublesome intubation. A cut point of 0.45 was chosen due to high sensitivity of 73.3%, 49.5% specificity and 62% accuracy respectively.

Figure 18: ROC curve for probability of troublesome intubation among 200 patients.

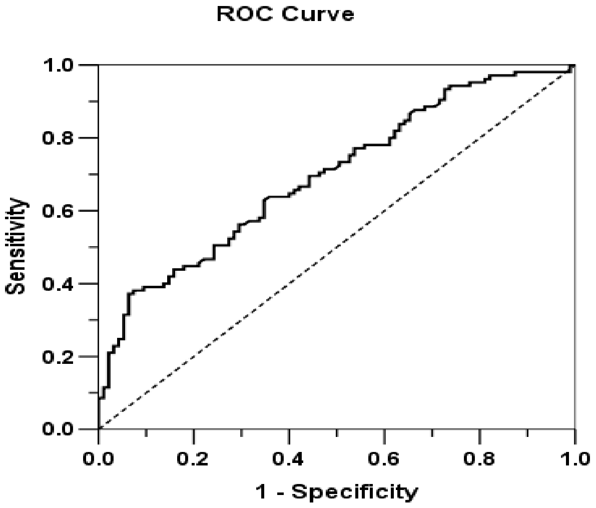


Table 18: Diagnostic values of final logistic regression model based on 200 patients

	Percent (95% CI)				
Cut point#	Sensitivity	Specificity	Accuracy	PPV	NPV
≥ 0.40	81.9 (73.2, 88.7)	37.9 (28.1, 48.4)	61.0 (53.9, 67.8)	59.3 (50.8, 67.4)	65.5 (51.4, 77.8)
≥ 0.45	73.3 (63.8, 81.5)	49.5 (39.1, 59.9)	62.0 (54.9, 68.8)	61.6 (52.5, 70.2)	62.7 (50.7, 73.6)
≥ 0.50	63.8 (53.9, 73.0)	64.2 (53.7, 73.8)	64.0 (56.9, 70.6)	66.3 (56.2, 75.4)	61.6 (51.3, 71.2)

Note: # Cut point for probability of troublesome intubation; NPV = Negative predictive value; PPV = Positive predictive value, CI = confidence interval.

To validate the final logistic regression model, this model was applied to another set of 80 patients. Probability of troublesome intubation for each subject was then calculated. Table 19 showed sensitivity, specificity, accuracy and predictive values of three selected cut points for probability of troublesome intubation. Cut point of 0.45 resulted in the sensitivity of 70.0%, specificity of 45.0% and accuracy of 57.5% respectively.

Table 19: Diagnostic values of final logistic model among 80 patients in the validation set

	Percent (95% CI)				
Cut point#	Sensitivity	Specificity	Accuracy	PPV	NPV
≥ 0.40	72.5 (57.2, 83.9)	35.0 (22.1, 50.5)	53.8 (42.9, 64.3)	52.7 (39.8, 65.3)	56.0 (37.1, 73.3)
≥ 0.45	70.0 (53.5, 83.4)	45.0 (29.3, 61.5)	57.5 (45.9, 68.5)	56.0 (41.3, 70.0)	60.0 (40.6, 77.3)
≥ 0.50	55.0 (38.5, 70.7)	57.5 (40.9, 73.0)	56.3 (44.7, 67.3)	56.4 (39.6, 72.2)	56.1 (39.7, 71.5)

Note: # Cut point for probability of troublesome intubation; NPV = Negative predictive value, PPV = Positive predictive value, CI = confidence interval.

<u>Adverse events</u>

Regarding adverse events, desaturation occurred in nine patients while performing mask ventilation and endotracheal intubation. Patients with IDS 11 and 12 experienced desaturation while other patients got IDS < 3. One case experienced tooth avulsion, and one case experienced tooth mobility. Eleven cases reported oral tissue injury characterized by abrasion at the lip, gum, tongue or soft palate, and sixteen cases complained of a sore throat within 24 hours postoperatively.

CHAPTER V

DISCUSSION AND CONCLUSION

5.1 Discussion

This is the first validation study to evaluate a predictive model in Thai obese patients for prediction of some degree of problematic endotracheal intubation. The cut-off point of 0.45 of the model revealed the sensitivity, specificity, positive predictive value, and negative predictive value were 73.3 (95% CI, 63.8- 81.5), 49.5 (95% CI, 39.1-59.9), 61.6 (95% CI, 52.5 - 70.2) and 62.7 (95% CI, 50.7 - 73.6), respectively.

The prediction of airway difficulty could help clinicians in a method of airway management. Nowadays, several alternative airway management devices increased in popularity as primary devices for obese patients underwent surgery in our institution. Those devices offered a better glottic visualization than conventional direct laryngoscopy. Among these tools, video-laryngoscopy was considered by many anesthesiologists as their first choice for intubation technique. Nevertheless, Paolini and colleagues proposed some potential drawbacks of the routine use of video-laryngoscopy in a recent review. Identifying that safety in airway management depended on multiple factors included clinical skills, efficient tools, planning and experience. Using video-laryngoscopes may provide a false sense of security, leading anesthesiologists to omit a basic airway examination.[37] Since these devices were expensive, they could not be provided to all hospital levels. In addition, data had not proved the cost-effectiveness and safety of using sophisticated devices for first-line airway management. A predictive model of troublesome intubation was needed.

An ideal model for prediction of difficult intubation should have perfect sensitivity and specificity. However, the predictive performance of the model was not always in a perfect situation. Sensitivity and specificity were dependent on each other, i.e., an increase in one of them usually results in a decrease in the other. A decision of which cut-point of the model was appropriate was based on whether sensitivity and specificity was more important. We created the model in order to early detect of Thai obese patients with had some degree of problematic conventional endotracheal intubation. As a result, a model with a good sensitivity was chosen to be our predictive model.

We compared the predictive performance of our predictive model with the existing model in Table 20. The Mallampati classification was the most common variable which was used to predict difficult intubation. The Neguib's model seemed to be a best model because they offered an optimized predictive performance. Nevertheless, this model derived from general patients, and the variable "height" was not the variable that clinicians almost always used to predict difficult intubation. As for Wilson Risk Sum Score and Simplified Score Model described by Arne et al, the sensitivity of both models was lower than our model. Furthermore, authors did not report multicolinearity or interaction of each variable and variables in the final models were not user friendly.

Table 20: Predictive performance compared between our model and three existing predictive models.

Model	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)
Our model	73.3 (63.8, 81.5)	49.5 (39.1, 59.9)	61.6 (52.5, 70.2)	62.7 (50.7, 73.6)
Wilson model	40.2 (30.0, 50.0)	92.8 (88.0, 98.0)	25.6 (NA)	96.2 (NA)
Arne model	54.6 (45.0, 65.0)	94.9 (90.0, 99.0)	39.7 (NA)	97.1 (NA)
Neguib model	81.4 (74.0, 89.0)	72.2 (63.0, 81.0)	15.3 (NA)	98.4 (NA)

Note: PPV = Positive predictive value; NPV = Negative predictive value; CI = confidence interval; NA = not available.

Preoperative airway assessment was important in the detection of patients at risk of difficult airway management. Shiga et al, reported a meta-analysis of bedside screening test performance. This systematic study composed of 50,760 patients enrolled from 35 studies. The populations of these studies were non-homogeneous, including morbidly obese, obstetric, gynecologic and diabetic patients underwent otolaryngology or general surgery. Four types of tests, namely, the Mallampati classification, the thyromental distance, the sternomental distance and the inter-incisor gap, were commonly used to predict difficult intubation. However, each test yielded poor to moderate pooled sensitivity (22-62%), but good pooled specificity (82-97%).[12] The authors concluded that the clinical value of bedside screening tests for predicting difficult intubation was limited. We proposed one possible factor could come from the inter-observer reliability. The concern arising from the interpretation of these tests was how good the inter-observer reliability was. It was still uncertain whether true prediction was possible. Since tests with low reliability estimates were not valid, the results would have unreliable predictive value. Our study confirmed the reliability of each test by describing the tests adequately and training the raters from each institution in the same technique to ensure favorable results before initiation of the study.

The incidence of airway difficulty of published literature varied according to the target population and the definition of airway difficulty. Nowadays, there is no universally accepted definition of difficult airway. The American Society of Anesthesiologists (ASA) Task Force on Management of Difficult Airway divided the difficult airway into four components: difficult tracheal intubation, difficult laryngoscopy, difficult mask ventilation and difficult laryngeal mask airway ventilation. Most studies concentrated on difficult intubation with different definitions. The ASA Task Force on Management of Difficult Airway described difficult intubation as intubation when tracheal intubation required multiple attempts, in the presence or absence of tracheal pathology, or an inability to place an endotracheal tube within ten minutes or three attempts by an experienced practitioner with at least two years full-time experience in anesthetics[7] A number of definitions of difficult intubation sometimes referred to difficult rigid laryngoscopic view, defined by poor glottic visualization or a high grade laryngeal view or failure to see the glottis by line of sight, or due to laryngeal or tracheal distortion or narrowing. Cormack and Lehane described the difficult tracheal intubation in obstetric patients by illustrating a scheme for views of the laryngeal inlet while performing laryngoscopy. This scheme has become a standard measurement of glottic views, and facilitates communication between researchers and clinicians. Grade 1 corresponds to the vocal cords were completely visible; Grade 2 to a view in which only the arytenoids were visible, Grade 3 to only the epiglottis was visible; and Grade 4 to the epiglottis was not visible. The authors concluded that Grade 3 and Grade 4 views were rare and likely to be difficult to manage.[38] Nonetheless, both definitions could not predict the difficult intubation in all situations. For example, Arné et al studies in 1,200 patients underwent general and otolaryngologic surgery, and they found that many of the grade III and grade IV views were not always associated with the occurrence of difficult intubation in general population, as many of the patients with the Cormack-Lehane Grade III and Grade IV views were actually easy intubation.[21]

The IDS score was utilized to define the difficult intubation in this study. Adnet et al proposed a quantitative scale of intubation difficulty in 1997. In our report, we did not record time to intubation. There were 22 cases corresponded to Cormack-Lehane Grade III, and there were two cases corresponded to Cormack-Lehane Grade IV. Patients with IDS 12, 11 and 6 were identified as Cormack-Lehane Grade IV, Grade IV and Grade II, respectively (data not demonstrated).

The incidence of difficult intubation of our report seemed to be a low value compared to other previous studies in Thailand. Ittichaikulthol et al (2010) conducted a prospective study in 1,888 adult general patients. Difficult laryngoscopy (grading by Cormack-Lehane Grade III and IV) occurred in 3.2%.[27] These different may be because firstly, we excluded the population that had high risk for difficult intubation from our target population. Some colleagues criticized that this was selection bias. However, we confirmed that the exclusion criterion was reasonable because our target population was obese patients who have no outstanding features of problematic patients. Secondly, most patients enrolled in our study were underwent operation at University hospital which could offer good facility and experienced anesthetic personnel. As a result, difficult intubation occurred in only 0.5% in Siriraj Hospital.

According to the previous studies which utilized IDS scores to identify difficult intubation, the incidence of difficult intubation was also much higher than in our report. Juvin et al (2003) conducted a study in obese patients in France. The authors reported that there were 20 obese patients out of 129 obese patients (15.5%) got IDS scores ≥ 5.[16] This different results may be because, firstly, obesity in different ethnic groups results in different anatomic features of the airway. Secondly, our protocol was not strict for the first time for airway management. To date, the management was at the discretion of in-charge anesthesiologists according to safety aspect. They could choose any types of blades and patients' position. They also decided to utilize a stylet if they considered that it was necessary. As a result, the incidence of difficult intubation in this study was very low.

5.2 Conclusion

This was the first study that provided a model for predicting troublesome intubation for Thai obese patients. Although predictive performance of our model was not perfect, the selection of variables and the foundation of the final model was an evidence-based process and reliable. Randomly selected study participants and inflation of the sample size from a multi-center study would increase the incidence of difficult intubation resulted in a capacity to develop a model which had more sensitive and specific to predict difficult intubation.

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VITA

Qualification and Education:

- Cert. of clinical research fellow, University of Washington, USA.
- Dip. Thai Board in Anesthesiology.
- M.D., Grad. Mahidol University.

Specialty: Anesthesiology

Position: Assistant Professor

Areas of Interest: Perioperative oxygen therapy, Anesthesia for liver transplantation. Airway management.

Office: Department of Anesthesiology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

Email: arunotai.sir@mahidol.ac.th

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