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Original Article

Comparison of Incidence of hypoxia during modified rapid sequence induction and an alternative technique: a prospective randomized controlled trial

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Abstract: Background: We evaluated the effects and safety of an alternative technique for rapid sequence intubation in children predicting to have high risk of pulmonary aspiration in this prospective, randomized, placebo-controlled study. Methods: One hundred sixty-five children predicting to have high risk of pulmonary aspiration were randomly allocated to spontaneous breathing maintained induction and intubation group (Group S) and the modified rapid sequence group (Group C). The primary outcome was the incidence of hypoxemia around the intubation period, which was defined as SpO_2<90% at any time during the induction and 10 min after the endotracheal intubation. Secondary outcomes included the incidence of pulmonary aspiration, gastroesophageal reflux and other major adverse events associated with the induction and intubation. Results: There were no differences in the incidence of hypoxemia around the intubation period between Group C and Group S; 25.9% vs. 14.8% (P=0.079). The incidence of severe hypoxemia appeared higher in Group C than Group S but not statistical significance, 6.2% vs. 2.5% (P=0.246). Simultaneously, gastroesophageal reflux (upper esophageal pH≤4) was detected in 4.93% children in Group C and 2.47% in group S, which was not significantly different between the two groups (P=0.552). There were no witnessed aspirations in all subjects. Conclusion: Sevoflurane based deep sedation with spontaneous respiration maintained technique is not superior to modified rapid sequence induction but can be an alternative technique for anesthesia induction for those predicting to have high risk of aspiration in children.

Keywords: Aspiration, rapid sequence induction, sevoflurane, hypoxemia

Introduction

Postoperative respiratory complications remain a major problem in surgical patients. One retrospective study carried out in 1980s showed that the incidence of aspiration was estimated at 1/2131 and the children and the elderly were most vulnerable [1]. However, it is possible that some silent aspirations were undetected by the above studies. The largest series of pulmonary aspiration were reported by the The Australian Incident Monitoring Study (AIMS) group. In total 5000 incidents, 133 cases of aspiration were reported, death ensued in five cases, 20% were children [2]. This paper reminded us "Aspiration remains an important anesthetic related morbidity". The risk factors included full stomach, bowel obstruction, abdominal pain, diabetes or associated trauma with poor stomach emptying [3].

Rapid sequence intubation (RSI) is the gold standard for securing air way at the earliest possible time after a patient loses consciousness in those patients vulnerable to regurgitation of gastric content and pulmonary aspiration. Since bag-mask ventilation (BMV) may inflate the stomach increasing the risk of vomiting and aspiration, any form of mask ventilation is not recommended [4, 5]. Thus, patients are preoxygenated for 3-5 minutes to prevent hypoxia during RSI. However, in children it may not be possible to get their cooperation for mask holding while awake before induction. Hence RSI has been modified to include gentle ventilation within a pressure of 10-12 cm H_2O. Additionally, there is a concern of distortion of laryngeal view after cricoid pressure especially in children which made intubation more difficult.

We designed an alternative technique to avoid cricoid pressure. In our technique patient is allowed to breath spontaneously at induction. The duration of induction might get prolonged. This study was undertaken to compare to incidence of hypoxia at induction with both modified RSI and alternative technique.

Materials and methods

After obtaining ethical approval from local institutional ethics committees of West China Hospital, this prospective randomized, doubleblindtrial was conducted at West China Hospitalfrom April 2011 to March 2014. Our study protocol was registered at www.chictr.org (ID: ChiCTR-TRC-12002163), which was in line with the principles of the Declaration of Helsinki. One hundred sixty-five children, predicting to have high risk of aspiration (Table S1), were recruited in our study. The exclusion criteria included potentially difficult airway, allergy to anesthetic, history or family history of malignant hyperthermia, history of asthma or bronchospasm, and contraindications of succinylcholine or rocuronium. Written informed consent was obtained from all subjects before randomization. Patients were assigned to either Group S or Group C by a table of computer-generated random numbers. Group assignments were sealed in sequentially numbered opaque envelopes.

Upon arrivingon the OR, all patients received standard monitoring, including electrocardiogram, noninvasive blood pressure and pulse oximetry. Then, atropine 0.02 mg/kg and midazolam 0.1 mg/kg (up to 2 mg) were administered intravenously for all subjects. In Group S, to achieve sufficient deep sedation but maintaining adequate spontaneous respiration, a cocktail of anesthetics was applied. The child received 2% to 4% sevoflurane inhalation with the fresh gas flow set at 5 L/min (same concentration that primed the respiratory circuit) with tidal volume breathing. At 2 min after inhalation, fentanyl 1 μg/kg was administered. At 5 min, propofol 0.5~1 mg/kg was given and followed with topicalization of the airway by spraying 2% lidocaine over the laryngopharynx. At 8 min, intubation was performed under spontaneous respiration. No manual mask ventilations were performed unless SpO_2 dropped to 90% prior to intubation. Muscle relaxants and more fentanyl were administered after endotracheal intubation was confirmed. In Group C, children were preoxygenated with 100% oxygen with fresh gas flow set at 5 L/min for 4 minutes (if the patients fought the mask, propofol 0.5 mg/kg IV was administered). Anesthesia was induced with fentanyl 2 ug/kg, propofol 3 mg/kg mixed with lidocaine 1.5 mg/kg. Cricoid pressure was applied when the lash reflex was absent (except in children under 1 year old) and succinylcholine 2 mg/kg IV or rocuronium 1.5 mg/kg was administered. After apnea for 1 minute (or 30 second if body weight less than 5 kg), intubation was performed. Gentle mask ventilation (inspiratory pressure less than 12 cm H_2O) was allowed if SpO_2 dropped below 90% prior to intubation.

The primary outcome of this study was the incidence of hypoxemia, which is defined as SpO_2<90% during the induction and 10 min after the endotracheal intubation. Hypoxemia is arbitrary subdivided into moderate hypoxemia (SpO_2 89-80%) and severe hypoxemia (SpO_2<80%). The secondary outcomes were the incidence of witnessed pulmonary aspirations and gastroesophageal reflux (upper esophageal pH≤4) during induction and intubation. The rate of assisted mask ventilation, the rate of controlled mask ventilations, Cormark&Lehane classification of vocal cords exposure and intubating conditions scores (ICS) (Table S2) were also documented [6]. Adverse events such as bradycardia (HR<60 bpm), tachycardia (HR increases more than 30% of the basic value), hypertension (SBP increases more than 30% of the basic value), hypotension (SBP<70 mmHg), laryngospasm, coughing and mask intolerance during general anesthesia induction and tracheal intubation were recorded carefully.

The primary outcome was the incidence of hypoxemia. Our sample size calculation was performed based on the comparison of proportion of patients with hypoxemia between groups using the Z-test for proportion comparison. According to our pilot study (n=30), the incidence of hypoxemia in Group C was 26.7% vs. 10% in the Group S. A power analysis using a type I error estimate of 5% (α=0.05) and a power (1-β) of 80% indicated that a sample of 75 subjects per group would be required. Allowing for an approximately 10% incomplete

Table 1. Patients' demographics, surgical categories and comorbidities

Characteristics	Group C (n=81)	Group S (n=81)	*P* value
Sex: male, n (%)	60 (74.1)	63 (77.8)	0.581
Age (months): median (IQR)	6 (2-17.5)	6 (2-17)	0.742
Weight (kg): median (IQR)	6.5 (3.55-11)	7 (3.50-9.80)	0.321
Body mass index (kg/m^2)	13.70±2.89	13.52±2.87	0.654
ASA			0.433
II: n (%)	39 (48.1)	31 (38.3)	
Iain (%)	38 (46.9)	46 (56.8)	
IV: n (%)	4 (4.9)	4 (4.9)	
Distribution of risk of aspiration			0.749
Elective surgery (%)	67 (82.7)	67 (82.7)	1.000
Congenital pyloric obstruction	12 (14.8)	8 (9.8)	
Congenital mega colon	21 (25.9)	19 (23.5)	
Esophageal stenosis	4 (4.9)	3 (3.7)	
Duodenal stenosis or obstruction	2 (2.5)	5 (6.2)	
Congenital biliary atresia	7 (8.6)	8 (9.9)	
Abdominal giant tumour	7 (8.6)	8 (9.9)	
Congenital intestinal malrotation	7 (8.6)	2 (2.5)	
Congenital diaphragmatic hernia	3 (3.7)	7 (8.6)	
Mackles diverticulum	3 (3.7)	2 (2.5)	
Congenital anal atresia	1 (1.2)	5 (6.2)	
Emergency surgery (%)	14 (17.3)	14 (17.3)	0.441
ileus	3 (3.7)	6 (7.4)	
Acute intussusception	4 (4.9)	1 (1.2)	
Incarceration of Inguinal hernia	4 (4.9)	4 (4.9)	
Gastric perforation	1 (1.2)	0	
Upper gastrointestinal hemorrhage	0	1 (1.2)	
Craniocerebral injury	2 (2.5)	2 (2.5)	
Comorbidities (%)	10 (12.3)	14 (17.3)	0.776
Cardiac Disease	2 (2.5)	4 (4.9)	0.439
Atrial septal defect (ASD)	2 (2.5)	3 (3.7)	
Kawasaki disease	0	1 (1.2)	
Pulmonary Disease	4 (4.9)	6 (7.4)	0.389
Pneumonia	4 (4.9)	5 (6.2)	
Pleural effusion	0	1 (1.2)	
Liver disease	2 (2.5)	2 (2.5)	0.333
Infant hepatitis syndrome	2 (2.5)	0	
Decompensated cirrhosis	0	2 (2.5)	
Gravis type craniocerebral injury	2 (2.5)	1 (1.2)	0.570
Shock	0	1 (1.2)	1.000

Group C=control group; Group S=sevoflurane group; IQR, interquartilerange; ASA, American society of Anesthesiologists physical status classification; SD, standard deviation. The *P*-value (age and weight) was from Mann-whitney test. Data were presented as numbers of patients or mean ± SD. There were no differences between the two groups.

follow-up or dropout, a total of 166 subjects were enrolled in this study. Statistical analysis was performed by using SPSS 19.0 (SPSS Chicago, IL, USA). For continuous variables, data were reported as mean [standard deviation (SD)] or median [interquartile range (IQR)] when appropriate. The normality of distribution was assessed by the Shapiro-Wilk test. Parametric data were analyzed with the independent *t*-test. For categorical variables, frequencies (percentages) were presented by treatment groups and compared using the Chi-square test or Fisher's exact test as appropriate. A *P*-value of <0.05 was considered a statistically significant difference.

Results

We initially assessed 180 patients for eligibility to participate in this study. Of these, 15 patients did not meet the inclusion criteria, and the remaining 165 patients enrolled to the study. There were no differences in patients' characteristics, and surgical categories, distribution of aspiration risks and comorbidities as well as the ASA physical status (**Table 1**).

The overall incidence of hypoxemia was not statistically significant between the control group and the sevoflurane group. In Group C, the incidence of hypoxemia was 25.9% (95% confidence interval, CI: 16.5-35.3), moderate hypoxemia (SpO_2 89-80%) was found in 19.7% of patients (n=16), and severe hypoxemia (SpO_2<80%) in 6.2% of patients (n=5). In Group S, the incidence of hypoxemia was 14.8% (95% CI: 7.0-22.6), moderate hypoxemia (SpO_2 89-80%) was found in 12.3% of patients (n=10), and severe hypoxemia

Table 2. Incidence of hypoxia and aspiration

Outcome	Group C	Group S	*P* value
Hypoxemia: n (%)	21 (25.9)	12 (14.8)	0.079
Moderate hypoxemia (SpO_2 80-89%)	16 (19.7)	10 (12.3)	
Severe hypoxemia (SpO_2<80%)	5 (6.2)	2 (2.5)	0.246
ASA II	9/39	3/31	0.204
ASA III	10/38	9/46	0.462
ASA IV	2/4	0/4	0.239
Witnessed aspiration: n	0	0	
Gastroesophageal reflux: n (%)	4 (4.9)	2 (2.5)	0.552
The upper esophageal pH: median (IQR)	6.0 (5.5-6.5)	6.0 (5.5-6.5)	0.451
Chest X-ray: n			
No Chest x-ray evidence	41/81	39/81	
Right lower zone*	3/40	1/42	
Left lower zone*	1/40	1/42	
Double lung texturefuzzy	4/40	7/42	
Clear x-ray	32/40	33/42	

Values are mean (SD); IQR, interquartile range. *Typical signs of chest X-ray of aspiration pneumonitis were an infiltrate in a characteristic bronchopulmonary segment.

Table 3. The Rate of mask ventilation and intubation conditions

	Group Cn (%)	Group Sn (%)	*P* value
Assisted mask ventilation	3 (3.7)	7 (8.6)	0.328
Controlled mask ventilation	8 (9.9)	4 (4.9)	0.370
Larygoscopy Views			
C&L			
I	74 (91.3)	75 (92.6)	0.375
II	5 (6.2)	2 (2.5)	
III	2 (2.5)	4 (4.9)	
IV	0 (0)	0 (0)	
ICS (IQR)	5.0 (5.0-5.5)	5.0 (5.0-6.5)	<0.001

C&L=Cormark&Lehane classication; ICS=Intubating condition scores; IQR=interquartilerange.

(SpO_2<80%) in 2.5% of patients (n=2). The differences in severe hypoxemia did not reach statistical significance (P>0.05). The distribution of hypoxemia among various ASA physical statuses had no significant differences (**Table 2**). There were no witnessed aspirations in both groups during induction periods. In total, 82 children had postoperative chest X-ray examinations. New findings were observed in 8 patients in Group C and 9 patients in Group S (see **Table 2**). Among them, 6/82 showed a typical signs of aspiration pneumonitis on chest x-ray examination, 4/40 in Group C and 2/40 in Group S. When upper esophageal pH≤4, gastroesophageal reflux was suspected, it was detected in 4/81 patients in Group C and in 2/81 patients in Group S with no differences between the two groups (P=0.552). These children showed no signs of wheeze, crackles ortachypnea postoperatively. No abnormalities were found by lung auscultation followed the endotracheal intubation and postoperative chest x-ray examination, thus ruling out the possibility of pulmonary aspiration.

As shown in 4.9% in **Table 3**, Group S and 9.9% in Group C accepted controlled mask ventilation during induction process. The laryngoscopy views were similar in both group C and Group S. Only 2.5% in Group C and 4.7% in Group S showed Cormark& Lehane classication (C&L) III and no children presented as (C&L) IV. The intubating condition scores (ICS) were lower in Group C than those in Group S (P<0.05). Endotracheal intubation and induction complications besides hypoxemia were recorded in **Table 4**. Group S suffered an unexpected high rate of coughing (23.17%, P<0.001). The cough happened at the moment that the tracheal tube went through the vocal cords. None of these patients developed laryngospasm or bradycardia. Hemodynamic data during anesthesia induction and tracheal intubation were shown in **Figure 1**. The heart rate in Group S was increased slightly but had no overall significant differences compared with Group C. In this two groups, we noticed that MAP was slightly higher in Group C than that in Group S after anesthesia induction, but the difference did not achieve statistical significance (P>0.05).

In the follow-up visits on postoperative 1, 3, 7 day, there were no serious adverse events reported in either group. No children experienced vomiting during the observing period in

Table 4. Complications (besides hypoxemia)

Complications (besides hypoxemia)	Group C n (%)	Group S n (%)	*P* value
Laryngospasm	0	0	
Coughing	0	19 (23.5)	
Hypertension (SBP increases more than 30% of the basic value)	0	2 (2.5)	0.497
Hypotension (SBP<70 mmHg)	5 (6.2)	1 (1.2)	0.210
Tachycardia (HR increases more than 30% of the basic value)	7 (8.6)	7 (8.6)	1.000
Bradycardia (HR<70 bpm)	0	0	
Mask intolerance (children fighted against mask)	9 (11.1)	5 (6.2)	0.263

SBP=systolic blood pressure; HR=heart rate.

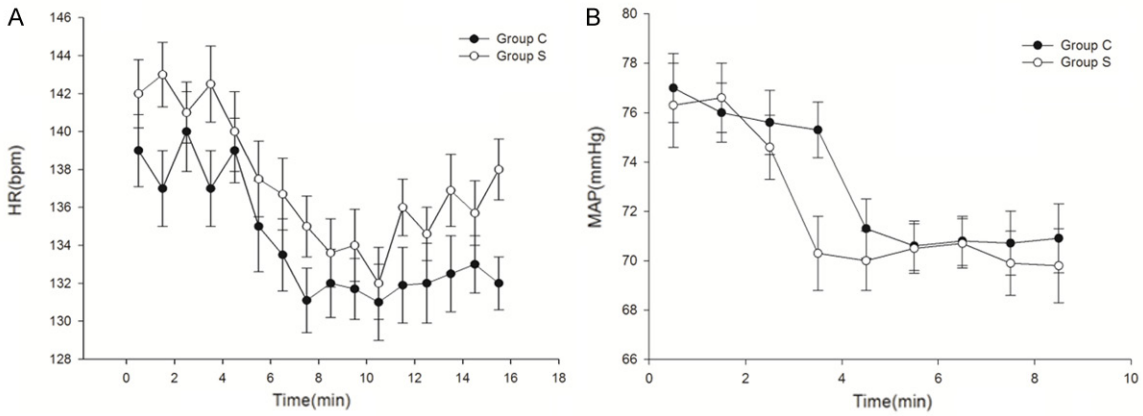

Figure 1. Data of heart rate and mean arterial pressure during anesthesia induction and tracheal intubation. HR= heart rate. Data were expressed as mean ± SD. There were no differences between the two groups.

the pediatric ward. And we found no children showed signs of reflux like dysphagia, wheeze, cough, etc. The ICU staying time were 2 (0-5) days and 3 (0-5.5) days in the Group C and Group S, respectively (P=0.798). Hospital stay was 11 (7.5-19.5) days and 13 (9.5-18.5) days in Group C and Group S, respectively (P=0.643).

Discussion

Oxygen hemoglobin desaturation is a feared condition when performing anesthesia induction for children. It would be far more stressful when their apnea tolerance further reduced by surgical problems such as decrease of pulmonary capacity by upward movement of diaphragm. For those considered to have high risk of aspiration, we were taught or trained to apply either rapid sequence induction/intubation or some forms of modified versions. The most common complications during RSI are hypoxia, particularly in small children weighing 10-19 kg [7]. Our experiences told us that it is worse in infants smaller than 10 kg. Poor preoxygenation and fear of mask ventilation are the key reasons resulting in hypoxia in RSI process. In this study, we attempted to use a new approach which is able to provide good preoxygenation and almost no need of positive ventilation via mask during induction process for children predicting to have high risk of aspiration. We have found that this new measure is as good as modified rapid sequence induction. It demonstrated relatively low incidence of oxygen desaturation and no incidence of witnessed aspiration considering the majority of children involved in our study were infants and complicated with abdominal problems.

The new measure we used is sevofurane based deep sedation muscle relaxants sparing protocol. We know that children can maintain spontaneous respiration and achieve appropriate depth of anesthesia at a certain concentration of sevoflurane. To avoid the application of high concentration of sevofurane, some other anesthetics such as midazolam and low dose fentanyl were combined with sevoflurane during

the induction. Very low dose propofol was administered before local anesthetic laryngopharyngeal spraying and intubation. Intubation was carried out with the child spontaneously breathing. No manual positive ventilation is needed unless the first intubation attempt failed or there is apnea. In our experimental (Group S) group, we found that only 4.9% children needed controlled mask ventilation and 8.6% received gentle manual assisted ventilation. In terms of the attempts of manual ventilation via mask, the experimental group is not superior to the control group which used a modified rapid sequence intubation. This is little out of our expectation. It is the same as the incidence of hypoxia and severe hypoxia. In both groups, the incidence of hypoxia was high, 25.9% in the control group and 14.8% in the sevoflurane group. Most of them were moderate hypoxemia. The incidence of severe hypoxemia appeared lower in sevoflurane group but it did not reach statistical difference. Gencorelli FJ reported that the incidence of moderate hypoxemia and severe hypoxemia were 1.9% and 1.7% respectively amongst 1070 children aged 3-12 undergoing RSI [7]. Diego N recently analyzed a study of 144 pediatric patients younger than 3 years undergoing RSI [8]. Although all of them were gently ventilated, five children (3.5%) developed significant hypoxemia. The incidence of hypoxemia was much higher in our study. We think the reasons are as follows: (1) children we recruited in our study were relatively small with age median at 6 months and weight median about 7 kg. (2) Most children suffered from intestinal obstruction. They were at high risk of aspiration due to the increase of stomach-abdominal pressure. Their abdominal breathing was inhibited and their diaphragms were moved upwards causing significant reduction of oxygen reserve and insufficiency of preoxygenation. (3) Some children were complicated with pulmonary and cardiac comorbidities. (4) We cannot exclude outcome variations among different investigators. There were about 10 anesthesiologists participating in this study. Some of them are subspecialized in pediatric anesthesia but some of them are general anesthesiologists rotated to pediatric anesthesia team. Nevertheless, you either use modified rapid sequence intubation or sevoflurane based spontaneous respiration protocol, hypoxemia and even severe hypoxemia are common in small children. In the sevoflurane group, most desaturation occurred at the moment endotracheal tubes passed through the vocal cords. Coughs and breath holding are the main reason. This is partly due to misjudgment of the depth of sedation and insufficient local anesthesia, which may be improved by proper training and experience. In the modified rapid sequence group, hypoxemia was caused by poor oxygen reserve partly due to the surgical pathophysiological condition as well as inadequate preoxygenation. This has demonstrated that preoxygenation is a problem in children during RSI process. Appropriate sedation is necessary to let the child accept the mask. Preoperative mask preconditioning in combination of midazolam administration and sevoflurane inhalation may be helpful [9]. Finally, there were no bradycardia or cardiac arrests and other severe adverse events happened in both groups.

In pediatric anesthesia, the main cause of regurgitation and aspiration during induction are vomiting and passive reflux. Vomiting often occurs in the process of conscious intubation or in inadequate depth of anesthesia during induction [10]. One of the concerns for our sevoflurane based deep sedation with spontaneous respiration maintained technique is whether it would induce vomiting and reflux. There was no vomiting and no witnessed aspiration. Since there is a lack of specific diagnostic criteria for postoperative aspiration, we performed chest X-ray for about 50% of the children involved in our study to detect whether there was silent aspiration. Among them, 6/80 showed a typical signs of aspiration pneumonitis on chest x-ray examination, 4/40 in Group C and 2/40 in Group S. They did not have preoperative respiratory comorbidities and they all showed slight or no corresponding clinical symptoms postoperatively. As the literature suggested, aspiration may have no consequences at all in up to 50% or may only show a mild clinical course [11]. It might not be possible to separate a true association between a symptom and reflux from a chance association due to the frequency of episodes of reflux. The upper esophageal pH detected at the level of lower edge of cricoid cartilage is used to monitor gastroesophageal reflux (pH<4). In our study, 6 (4 in Group C, 2 in Group S) showed gastroesophageal reflux but none of them presented symptoms or signs of pulmonary aspira-

tion. Our study clearly showed that children in the sevoflurane group did not show higher incidence of reflux than the control group. It is confirmed that low concentration of sevoflurane would not change the lower esophageal sphincter pressure and barrier pressure [12]. Therefore, even though we haven't provide evidence that sevoflurane based deep sedation with spontaneous respiration maintained technique is superior to MRSI for prevention of pulmonary aspiration, it appears as safe as MRSI and can be used as an alternative measure for anesthesia induction predicted to have high risk of aspiration, particularly for infants and small children.

There are limitations in our study, since the incidence of pulmonary aspiration is relatively low. We had set up the incidence of hypoxemia as the primary outcome and calculated the sample size according to our pilot study. Finally, we completed all the cases but we didn't find a significant difference of hypoxemia incidence. Therefore, the evidence is weak to support the new technique we proposed for reducing the hypoxemia while preventing the aspiration in children. This is a single center study. We may need multi-center study to further prove its effectiveness and safety.

Conclusion

In summary, sevoflurane based deep sedation with spontaneous respiration maintained technique is not superior to MRSI but can be an alternative technique for anesthesia induction for those predicting to have high risk of aspiration in children.

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Disclosure of conflict of interest

None.

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Table S1. Preoperative Aspirations Risk Assessment

	Yes	No
1. Esophageal sphincter of oddi dysfunction	□	□
2. Full-stomach	□	□
Not correctly fasted		
Emergency surgery		
Delayed gastric emptying		
Intestinal obstruction		
Massive abdominal distention		
Diabetes mellitus		
Renal failure		
3. Impaired laryngeal reflexes	□	□
Cerebral injury		
Cranial nerve diseases		

Table S2. Intubating condition scoring

	1	2	3	4
Jaw relaxation	Complete	Slight tone	Stiff	Rigid
Laryngoscopy	Easy	Fair	Difficult	Impossible
Vocal cords	Open	Moving	Closing	Closed
Coughing	None	Slight	Moderate	Severe
Limb movement	None	Slight	Moderate	Severe

Score 1 represents the best possible condition and score 4 represents the worst one in each category. The best possible score is 5 and the worst possible score is 20 [6].