

# Effectiveness and Safety of a Novel Approach for Management of Patients with Potential Difficult Mask Ventilation and Tracheal Intubation: A Multi-center Randomized Trial

Ji-Ming Wang<sup>1</sup>, Er-Li Ma<sup>1</sup>, Qing-Ping Wu<sup>2</sup>, Ming Tian<sup>3</sup>, Yan-Yan Sun<sup>4</sup>, Jing Lin<sup>1</sup>, Liang Peng<sup>1</sup>, Qiang Xu<sup>2</sup>, Wei Wei<sup>3</sup>, Hong Tan<sup>3</sup>, Cen Yang<sup>4</sup>, Xiao-Qiang Li<sup>1</sup>, Yun-Xia Zuo<sup>1</sup>, Jin Liu<sup>1</sup>

<sup>1</sup>Department of Anesthesiology, West China Hospital, Sichuan University, Chengdu, Sichuan 610041, China

<sup>2</sup>Department of Anesthesiology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei 430000, China

<sup>3</sup>Department of Anesthesiology, Beijing Friendship Hospital, Capital Medical University, Beijing 100050, China

<sup>4</sup>Department of Anesthesiology, Xijing Hospital, The Fourth Military Medical University, Xi'an, Shaanxi 710000, China

## Abstract

**Background:** Patients with potential difficult mask ventilation (DV) and difficult intubation (DI) are often managed with awake intubation, which can be stressful for patients and anesthesiologists. This prospective randomized study evaluated a new approach, fast difficult airway evaluation (FDAE). We hypothesized that the FDAE approach would reduce the need for awake intubation.

**Methods:** After obtaining informed consent, 302 patients with potential DV/DI undergoing elective surgeries were randomly assigned to the FDAE group (Group E) and the control group (Group C). In Group E, patients were gradually sedated, and adequacy of manual mask ventilation during spontaneous breathing was assessed at various sedation levels. Awake intubation was applied in those with inadequate mask ventilation. In Group C, DI was evaluated under local anesthesia. However, the care team could intubate under general anesthesia if the vocal cords were visible. The primary outcome was the rate of awake intubations in both groups and the induction efficiency assessed by the induction time. The secondary outcome was the incidence of serious complications.

**Results:** The rate of awake intubation was significantly lower in Group E than that in Group C (5.81% vs. 36.05%,  $\chi^2 = 42.3$ ,  $P < 0.001$ ). The induction time was much shorter in Group E than in Group C ( $11.85 \pm 4.82$  min vs.  $18.71 \pm 7.85$  min,  $t = 5.39$ ,  $P < 0.001$ ). There was no significant difference in the incidence of intubation related complications between the two groups. Patients in Group E had a much lower incidence of recall (9.68% vs. 44.90%,  $\chi^2 = 47.68$ ,  $P < 0.001$ ) of the induction process and higher satisfaction levels than patients in Group C ( $t = 15.36$ ,  $P < 0.001$ ).

**Conclusions:** The FDAE significantly reduces the need for awake intubation and improves the efficiency of the intubation process without comprising safety in patients with potential difficult mask ventilation and DI.

**Trial Registration:** No. ChiCTR-TRC-11001418; <http://www.gctr.org/cn/proj/show.aspx?proj=1562>.

**Key words:** Airway Evaluation; Awake Intubation; Difficult Airway; Sevoflurane

## INTRODUCTION

The ability to identify a difficult airway based on physical examination predictors is usually inaccurate.<sup>[1-3]</sup> According to a recent report by Nørskov *et al.*,<sup>[4]</sup> of 188,064 cases in a Danish Anesthesia Database, 3154 (93%) difficult intubations (DIs) and 857 (94%) difficult mask cases were unanticipated. Furthermore, in cases predicted to be DIs 75% were not difficult to intubate and of those

**Address for correspondence:** Dr. Yun-Xia Zuo,

Department of Anesthesiology and Translational Medical Neuroscience Center, West China Hospital, Sichuan University, Guoxuexiang 37#, Chengdu, Sichuan 610041, China  
E-Mail: zuoyunxiahxa@qq.com

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predicted to be difficult to ventilate, 78% were easy to ventilate. Patients with anticipated difficult mask ventilation and/or difficult tracheal intubation often undergo “awake” tracheal intubation.<sup>[5,6]</sup> Awake intubation can be technically challenging for the anesthesiologist and psychologically stressful for patients.<sup>[7-9]</sup> Furthermore, awake intubation is not risk-free, as patients might experience adverse events such as obstruction or regurgitation during the process of securing the airway. Awake intubation usually requires fiberoptic bronchoscopy (FOB) guidance which is costly, not always readily available and requires kinesthetic skill and training to use.<sup>[10]</sup> Better prediction of patients who are difficult to mask ventilate or intubate would reduce the need for awake intubation.

Inhalation induction with the maintenance of spontaneous ventilation has been used as an alternative to awake intubation.<sup>[11-15]</sup> However, airway obstruction might occur with this technique after induction of general anesthesia. We developed a novel technique in which patients received a gradual induction of inhaled anesthesia with sevoflurane with simultaneous testing of airway patency through mask ventilation during the induction process. If at any stage mask ventilation became difficult, patients were awoken, and an awake tracheal intubation was performed. In this multicenter randomized trial, we compared our novel approach with the traditional approach of tracheal intubation in patients with the suspected difficult airway. We also assessed the safety of our technique. We hypothesized that our novel approach would reduce the need for awake tracheal intubation without compromising patient safety.

## METHODS

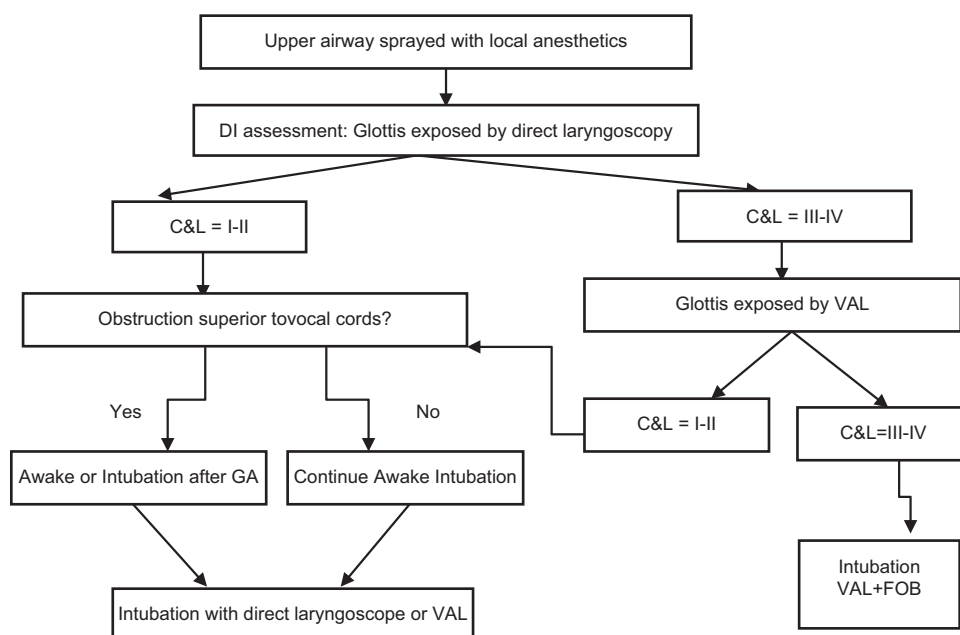
### Ethical approval

This prospective multicenter study (fast difficult airway evaluation [FADE] trial) was approved by the local institutional ethics committees of West China Hospital and followed by all participating hospitals. A written informed consent was obtained from each participant.

Four tertiary medical centers (West China Hospital of Sichuan University, Union Hospital of Tongji Medical College of Huazhong University of Science and Technology, Beijing Friendship Hospital of Capital Medical University, and Xijing Hospital of The Fourth Military Medical University) in China participated in this study from April 2011 to March 2014. We enrolled patients (age 18–65 years, ASA classification I–III) with a high risk of difficult ventilation and DI requiring tracheal intubation for their elective surgeries. Inclusion criteria were as follows: (1) patients with oral, upper airway and tracheal tumors or neoplasms; (2) patients with tracheal compression by cervical neoplasms or masses; (3) patients with tracheal deviation or stenosis caused by neck trauma, burns, surgical procedures, and radiotherapy; (4) patients with body mass index (BMI)  $\geq 30$ , Mallampati score III–IV and thyromental distance  $< 6.0$  cm;<sup>[16]</sup> (5) patients with obstructive sleep apnea (OSA) with Apnea-Hypopnea Index (AHI)  $\geq 15$ .

Exclusion criteria were as follows: (1) patients with severe airway obstruction who require awake intubation, for example, patients with a luminal transverse area of the trachea less than 1/3 its original size due to an intratracheal neoplasm, or external compression from tumor or mass around trachea; (2) patients unable to breathe in the supine position; (3) patients with complicated respiratory diseases including pneumonia, asthma, chronic bronchitis, pulmonary emphysema; (4) patients with a high risk of aspiration, including intestinal obstruction, full stomach, esophageal reflux; (5) patients with history or family history of malignant hyperthermia; (6) pregnancy.

Eligible patients with high risk of difficult ventilation and DI were screened and enrolled. The demographic information and detailed airway assessments of enrolled patients were documented preoperatively. Eligible patients were randomly assigned into two groups: the FDAE group (Group E,  $n = 155$ ) and the control group (Group C,  $n = 147$ ). The randomization was generated using SPSS statistical software, sub-stratified by center. The group assignment of each patient was concealed in a nontransparent envelope and opened according to the patient enrolled ID. Routine monitoring was established including electrocardiography, blood pressure, pulse oximetry (SpO<sub>2</sub>), and capnography. For each enrolled patient, atropine was administered intravenously to keep the airway dry, and ephedrine was used to prepare the patient’s nostrils in case there was a need for a nasal intubation. In Group C, patients received awake evaluation as per routine practice of the four medical centers. Vocal cord exposure was evaluated under topical local anesthesia initially in the awake state with light sedation. In brief, the airway was topically anesthetized with 2% lignocaine or 1% tetracaine. Midazolam (0.5 mg incrementally to a maximum of 2.0 mg) and fentanyl (20  $\mu$ g incrementally to a maximum of 100  $\mu$ g) were titrated based on the assessment of the care team [Figure 1]. In Group E, patients underwent FDAE process. After pre-oxygenation with 100% oxygen for 3 min, they were gradually sedated with sevoflurane inhalation while maintaining spontaneous breathing. The fresh gas flow was set at 6 L/min with initial inhaled sevoflurane of 1% and then raised at a rate about 1% in 2 min intervals up to 3%. Sedation levels were estimated by using Ramsay scoring and the Bispectral Index.<sup>[17]</sup> The degree of airway obstruction was assessed using the airway obstruction score (AOS),<sup>[18,19]</sup> a test of the adequacy of positive pressure ventilation through facemask (difficult ventilation test) was done between spontaneous breaths and measured using Han’s Mask Ventilation Score.<sup>[20,21]</sup> If AOS  $< 2$  or the Han score  $< 3$ , sevoflurane inhalation was kept at 3% until the loss of consciousness. When patients were asleep but AOS  $> 2$  or Han’s score  $\geq 3$ , an oropharyngeal airway was placed immediately. If the placement of the oropharyngeal airway did not improve the adequacy of positive pressure ventilation, sevoflurane was terminated and washed out using high fresh gas flow rates within a couple of min. These patients would then be awoken and intubated awake.



**Figure 1:** Algorithm in Group C ( $n = 147$ ). DI: Difficult intubation; GA: General anesthesia; VAL: Video-assisted laryngoscope; FOB: Fiberoptic bronchoscopy; C&L: Cormack and Lehane.

After evaluating ventilation in Group E, the attending anesthesiologist in charge of the case assessed (recorded by the investigator) the direct laryngoscopy (DL) grade using the Cormack and Lehane (C&L) classification.<sup>[22]</sup> If the C&L grade was  $\geq 3$ , video-assisted laryngoscopy with the Airtraq was used. For patients who had pathology causing airway obstruction superior to the vocal cords, muscle relaxants were administered before intubation if the C&L Grade was I or II with DL or video laryngoscopy with the Airtraq. However, in Group C, the care team decided (as their routine practice) whether to proceed with awake intubation when the C&L Grade was I or II. For those who had pathology inferior to vocal cords, the intubation was performed while maintaining spontaneous ventilation without using muscle relaxants. If the C&L grade was  $\geq III$ , intubation was conducted with the FOB as an adjunct [Figure 2].

The primary outcomes of this study were the rate of awake intubation in the two groups and the induction efficiency assessed by the induction time. The most important secondary outcome was the incidence of serious complications associated with the intubation process including cardiac arrests, “Cannot intubate, cannot ventilate” (defined as both mask ventilation and intubation were impossible followed by severe hypoxia), laryngospasm and pulmonary edema (defined according to standard definition), the need for an invasive surgical airway; The secondary outcomes included: (1) the rate of successful intubation by Airtraq or DL; (2) satisfaction of the patients.

A case report form was used to collect each participant’s information. Apart from demographic data and preoperative airway assessments, the following were recorded: the induction time, namely, the period from starting the local anesthetic spray in Group C or the initiation of sevoflurane

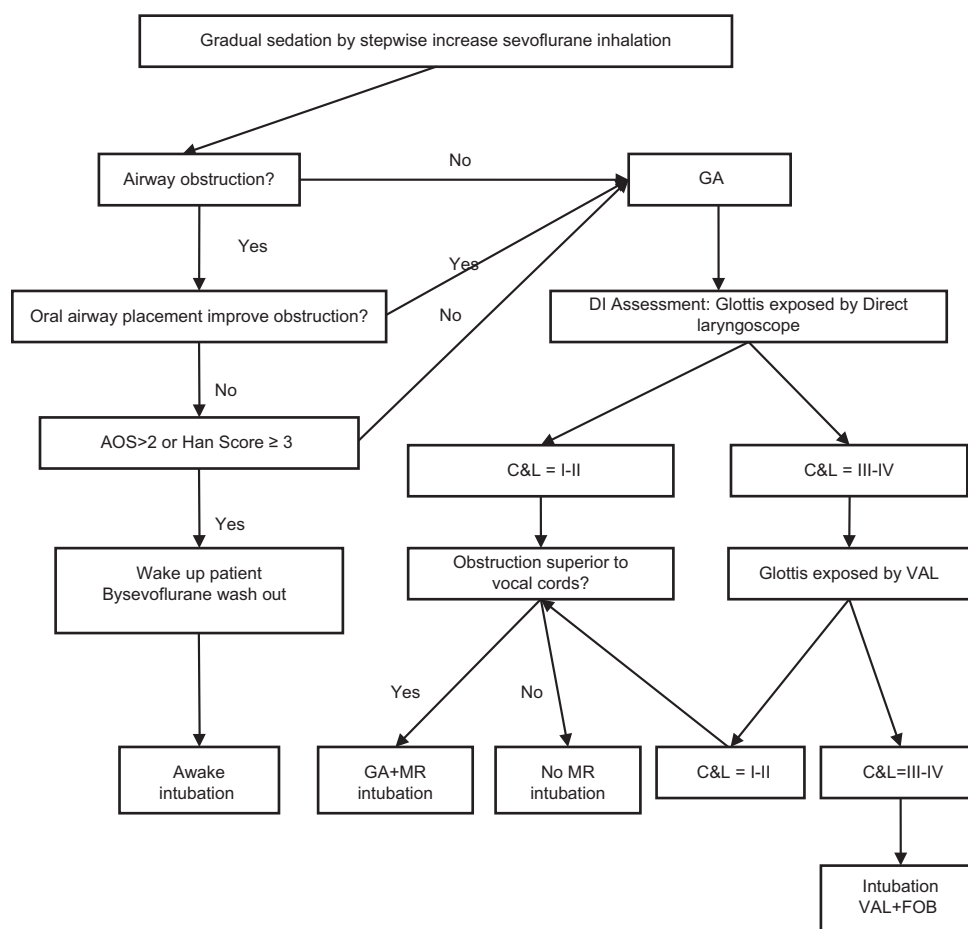
inhalation in Group E to the establishment of endotracheal intubation confirmed by end-tidal carbon dioxide. Patients were followed up until postoperative day 2. Patients’ satisfaction score (0 = dissatisfaction; 10 = very satisfactory) and recall for the intubation process were documented.<sup>[23]</sup> Postoperative adverse outcomes such as postoperative throat discomfort and hoarseness were documented in the follow-up visits.

### Statistical analysis

All comparisons were two-sided, and a value of  $P < 0.05$  was considered statistically significant. Data were presented as the mean  $\pm$  standard deviation (SD) or median with 95% confidence interval for non-Gaussian variables. Statistical analysis was performed with the SPSS 17.0 software (version 17.0, SPSS Inc., Chicago, IL, USA). Nonparametric data from the two groups were compared using rank sum tests. Comparison of percentages was performed using either a Chi-squared or Fisher’s exact test. Parametric data between the two groups were compared using the Student’s *t*-test. The sample size of this study was calculated based on our historic data and a pilot study. We assumed that application of FDAE would reduce the rate of awake intubation by 20%, with 5% being considered significant (one-side test) 242 patients would need to be enrolled. We estimated a dropout rate of enrolled patients of 20% giving a total number of patients of 291.

### RESULTS

Three hundred and fifteen patients underwent eligibility screening, 13 of them were excluded based on our exclusion criteria [Figure 3], 302 patients were randomized, 155 patients in Group E and 147 patients in Group C. There were no differences between the groups in age,



**Figure 2:** Algorithm of fast difficult airway evaluation ( $n = 155$ ). C&L: Cormack and Lehance; GA: General anesthesia; DI: Difficult intubation; AOS: Airway obstruction score; MR: Muscle relaxants; Han Score: Han's Mask Ventilation Score; VAL: Video-assisted laryngoscope.

height, weight, BMI, gender, and ASA classification (all  $P > 0.05$ ; Table 1). The majority (83.77%) of patients had OSA with  $AHI 61.19 \pm 19.60$  in Group E and with  $AHI 57.14 \pm 19.80$  in Group C ( $t = 1.63$ ,  $P = 0.11$ ; Figure 3). The Mallampati classification was  $\geq III$  in 81.29% and 87.07% of patients in Group E and Group C, respectively ( $Z = 1.43$ ,  $P = 0.15$ ; Table 1). In Group E, 94.19% of patients did not show signs of obvious airway obstruction and had  $AOS < 2$  or Han score  $< 3$  after the loss of consciousness. They were all intubated after general anesthesia induction. Only 5.81% of patients developed obvious airway obstruction after the loss of consciousness (AOS  $> 2$ ) with or without an oral airway. They failed to pass the difficult manual mask ventilation test with Han's score  $\geq 3$ . Since they were under spontaneous respiration, the  $SpO_2$  was maintained over 93%. They were awoken by discontinuing the inhaled sevoflurane. These patients were later intubated awake. In Group C, awake intubation was performed in 36.05% of patients, which was much higher than 5.81% in Group E ( $\chi^2 = 42.30$ ,  $P < 0.001$ ; Table 2).

The anesthesia induction time was  $11.85 \pm 4.82$  min in Group E versus  $18.71 \pm 7.85$  min in Group C ( $t = 5.39$ ,  $P < 0.001$ ; Table 2). There were no significant differences in the incidence of serious complications associated with intubation between the two groups, 1/150

in Group E versus 0/147 in Group C. No cardiac arrests, cannot ventilate, cannot intubate (CVCI), pulmonary edema, or emergency invasive surgical airway was required in either group. There was one patient who developed laryngospasm during the FDAE process. His  $SpO_2$  briefly dropped to 50% but resolved within 1 min after a bolus of propofol (30 mg) intravenously. The patient was then intubated after the loss of consciousness. No differences in minor injuries including injury to teeth, lips, pharynx, and nose bleeding were found between the two groups.

In the follow-up visit, only 9.68% of patients could clearly recall the induction process in Group E, versus 44.90% in Group C ( $\chi^2 = 47.68$ ,  $P < 0.001$ ; Table 3). The patient satisfaction scores for the induction experience were much higher in Group E (averaged at 9 out of 10) than those in Group C (averaged at 5 out of 10) ( $t = 15.36$ ,  $P < 0.001$ ; Table 3). For intubation, the rate of successful intubation after induction by DL in Group E was 18.71% versus 7.48% in Group C. There were 81.29% of patients in Group E intubated by Airtraq while 89.12% in Group C.

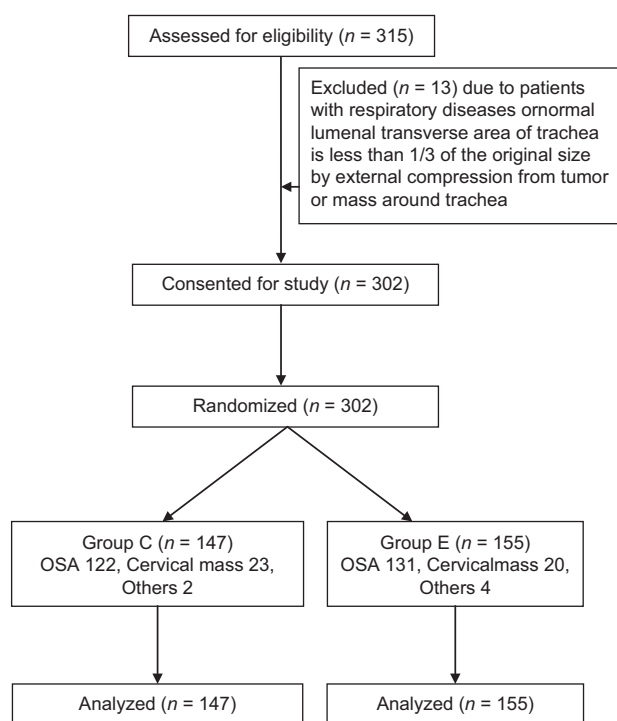
## DISCUSSION

It is well known that awake intubation is extremely stressful to patients and avoiding unnecessary awake intubation without

**Table 1: Demographic characteristics and preoperative airway assessments of patients with potential difficult mask ventilation and difficult intubation**

Characteristics	Group E (n = 155)	Group C (n = 147)	Statistics	P
Age (years)	39.75 ± 9.87	37.73 ± 10.62	1.71*	0.088
Gender (male/female)	140/15	126/21	1.52†	0.217
Height (cm)	170.27 ± 6.01	169.76 ± 6.71	0.26*	0.794
Weight (kg)	79.08 ± 12.11	78.92 ± 13.64	0.02*	0.986
BMI (kg/m <sup>2</sup> )	27.18 ± 3.23	27.29 ± 3.92	0.05*	0.964
ASA				
I	76	72	0.19‡	0.847
II	64	55		
III	15	20		
Mallampati classification				
I	7	1	1.43‡	0.153
II	22	18		
III	113	113		
IV	13	15		
Mouth opening (cm)	4.37 ± 0.89	4.30 ± 0.85	0.85*	0.394
Neck circumference (cm)	41.80 ± 3.19	41.92 ± 3.58	0.01*	0.990
Thyromental distance (cm)	7.46 ± 0.93	7.29 ± 1.11	1.90*	0.055

Data are expressed as mean ± SD or n. Group E: Using the new algorithm for fast difficult airway evaluation; Group C: Using awake evaluation. \*t value; †χ<sup>2</sup> value; ‡Z value. BMI: Body mass index; ASA: American Society of Anesthesiologists; SD: Standard deviation.



**Figure 3:** Flowchart of fast difficult airway evaluation trial. OSA: Obstructive sleep apnea.

compromising safety would improve the quality of patient care.<sup>[24]</sup> This study is the first to demonstrate that a new approach of incrementally increasing sedation level using inhaled sevoflurane while testing airway patency reduced the need for awake intubation without compromising patient safety. The results clearly showed that the majority of patients (94.19%) were able to maintain adequate spontaneous breathing and oxygenation even after loss of consciousness in patients with anticipated difficult airways. Only 5.81% of patients who did

not pass the positive ventilation test required awake intubation according to our FDAE protocol. Of these patients, they were able to maintain SpO<sub>2</sub> above 93% during the evaluation process since spontaneous respiration was maintained. For anticipated difficult airways, awake exposure of the vocal cords is routine practice. When the exposure is good, the patients may be intubated under anesthesia at the discretion of the supervising anesthesiologist. Therefore, the awake intubation rate in our control group was 36.05% instead of 100%. The study clearly showed that the new approach significantly reduced the need for awake intubation in patients anticipated to have difficult mask ventilation and/or intubation. The main advantages of this new approach are only provide awake intubation to those ones really need it, which would avoid stress and discomfort for the majority of patients who had potential DV/DI. If all the anesthesiologists are familiar with FDAE method, they would apply it frequently which might reduce none standard care of performing general anesthesia induction regardless the presence of DV/DI. Therefore, the new approach of FDAE for the management of difficult airway will enhance the clinical safety.

The efficiency of intubation is also another concern regardless of the intubation approach, asleep or awake. We all know that awake intubation is time-consuming. It is questionable whether the new approach could improve intubation efficiency. In this control group, the average induction time was 18 min with large individual variations. In the FDAE protocol group, the induction time was 36% lower with less variation. This indicates that the FDAE approach is not only effective but also reduces the anesthesia induction time for anticipated DMV/DI.

The results also showed that the risks of the new approach are not higher than that of our routine practice. The only event was a single episode of brief desaturation in one patient in

**Table 2: Outcomes of patients with potential difficult mask ventilation and difficult intubation**

Outcomes	Group E (n = 155)	Group C (n = 147)	Statistics	P
Primary outcomes				
Intubation after induction	146 (94.19)	94 (63.95)	42.30 <sup>†</sup>	<0.001
Awake intubation	9 (5.81)	53 (36.05)		
Induction time (min)*	11.85 ± 4.82	18.71 ± 7.85	5.39 <sup>‡</sup>	<0.001
Secondary outcomes				
DL intubation	29 (18.71)	11 (7.48)	12.99 <sup>†</sup>	0.002
Airtraq intubation	126 (81.29)	131 (89.12)		
FOB intubation	0	5 (3.40)		

Data are expressed as mean ± SD or n (%). \*One patient was excluded because the induction time is about 219 min in the control group due to poor local anesthesia; <sup>†</sup> $\chi^2$  value; <sup>‡</sup>t value. DL: Direct laryngoscopy; FOB: Fiberoptic bronchoscopy; SD: Standard deviation.

**Table 3: Satisfaction scores of anesthesiologists and adverse outcomes of patients with potential difficult mask ventilation and difficult intubation**

Items	Group E (n = 155)	Group C (n = 147)	Statistics	P
Recall of tracheal intubation	15 (9.68)	66 (44.90)	47.68*	<0.001
Sore throat	64 (41.29)	106 (72.11)	29.12*	<0.001
Patient satisfaction scores	9.28 ± 1.49	5.12 ± 3.01	15.36 <sup>†</sup>	<0.001
Anesthesiologists satisfaction scores	8.60 ± 1.62	4.86 ± 1.86	18.65 <sup>†</sup>	<0.001

Data are reported as mean ± SD or n (%). \* $\chi^2$  value; <sup>†</sup>t value. SD: Standard deviation.

the protocol group (1/150 vs. 0/147 in Group C). Based on this result, the sample size has to be over 100,000 to detect a statistical difference of hypoxemia between our new protocol group and the routine practice group. Although the risk of developing laryngospasm and failure of mask ventilation is present during the FDAE process, there is no guarantee that this would not occur under routine practice. In the clinical setting, some patients with potential DMV/DTI as the ones included in our study are induced under general anesthesia without proper testing; these patients would have the risk of developing CVCI resulting in severe hypoxia or death. It is not feasible because of ethical considerations to compare the safety our FDAE approach with direct general anesthesia induction.

We also assessed if the new approach was superior to routine practice in terms of discomfort, mental stress, anxiety, fear, and unpleasant memories for patients as described previously.<sup>[25,26]</sup> Patients undergoing the FDAE approach had much lower recall rates of the induction experience. They were much more satisfied with the intubation process when compared to routine practice. According to our study, the majority of patients with a high risk of difficult ventilation and DI do not have to suffer from the discomfort of awake intubation if the FDAE approach is applied. The FDAE approach not only helped the clinicians decide whether to secure the airway awake or asleep but also helped specify the intubation technique.<sup>[27,28]</sup> For anticipated difficult airway patients, FOB-guided intubation used to be the classic choice. However, with the advancement of video-assisted laryngoscopy, FOB is not necessary in most cases.<sup>[29]</sup> In our study, the vocal cords exposure was initially assessed under traditional DL in both groups. Although there were no differences in preoperative difficult airway assessments estimated by Mallampati classification *et al.*, the FDAE

approach had higher rates of intubation under DL which could save the usage of VAL. Patients in the FDAE group with C&L Grade  $\geq 3$  were all successfully intubated using the Airtraq. Unlike the control group, none needed FOB guidance. Therefore, the FDAE approach reduces the rate of DI, which is likely to save more medical resources.

Most clinical studies cited by difficult airway management guidelines are not randomized clinical trials. This is due to the nature of hardship to conduct a clinical trial in this type of patients who are at high risk during anesthesia induction. Anesthesiologists are usually under stress during induction process particularly when patients present potential difficult ventilation. To recruit the patients into a study would need more efforts from anesthesiologists. Therefore, there are a number of limitations to our study. First, due to the nature of the study, blinding was not feasible. Anesthesiologists who performed the airway assessment, intubation and recorded the procedures were aware of the intervention. Therefore, potential bias could occur due to lack of blinding. Second, our power analysis was based on the calculation of effectiveness, not on safety. Our sample size may be too small to assess the safety of the FDAE approach. Third, the intubation process in the control group may be old fashioned. However, it is still a common practice for expected difficult airways in most hospitals in China.

In conclusion, the FDAE approach to managing the airway of patients with potential DV/DI significantly reduces the need for awake intubation without compromising patients' the safety.

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## Conflicts of interest

There are no conflicts of interest.

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# 困难气道快速评估方案应用于潜在通气困难合并插管困难患者有效性和安全性评价的多中心研究

## 摘要

**背景:** 困难气道处理不当可能危及患者生命安全, 麻醉医生必需避免“不能通气, 不能插管”危急现象的出现。因此, 全身麻醉诱导前气道风险的评估甚为重要, 尤其是那些存在潜在通气困难和插管困难的病人。然而, 目前临床上还没有恰当的评价方法。本研究针对此类病人设计出一种快速困难气道评估方法(FDAE)即采用低浓度七氟烷吸入麻醉逐步加深镇静深度, 观察评估通气困难程度, 并据此决定全身麻醉诱导方法。本研究假设此方法能减少清醒插管。

**方法:** 将302例准备全麻下行择期手术的潜在通气困难的高危患者随机分为七氟烷快速评估组(简称E组; 155例)与局部麻醉评估对照组(简称C组; 147例)。前者采用低浓度七氟烷开始缓慢逐渐镇静, 观察气道通畅程度的改变和评估通气难易程度。根据患者对镇静的耐受程度选择全身麻醉诱导或者清醒诱导。对照组采用1%丁卡因或2%利多卡因局麻下行声门暴露, 根据声门暴露程度选择麻醉诱导和插管方法。观察主要指标是清醒插管率及诱导耗费时间, 次要指标是两组患者麻醉诱导期间并发症, 术后随访调查患者对麻醉诱导的满意度。

**结果:** 清醒插管率E组明显低于C组(5.81% vs. 36.05%,  $\chi^2 = 42.3, P < 0.001$ )。诱导时间E组明显短于C组, 两组诱导及插管的并发症没有统计学意义。E组术后随访病人对诱导评估的记忆低于C组患者(9.68% vs. 44.90%,  $\chi^2 = 47.68, P < 0.001$ ), E组满意度评分高于C组患者( $t = 15.36, P < 0.001$ )。

**结论:** 七氟烷吸入快速通气困难评估方法能降低清醒插管率, 缩短麻醉诱导时间, 提高患者舒适度。