Awake fiberoptic orotracheal intubation: a protocol feasibility study

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Abstract
Objective: To assess the feasibility of an awake fiberoptic intubation (AFOI) protocol.
Methods: We enrolled 40 patients with simulated difficult intubation. The protocol consisted of conscious sedation (midazolam, 0.03 mg/kg and sufentanil, 0.1 μg/kg), regional anesthesia, and intubation. The time, first-attempt intubation success rate, hemodynamic parameters, blood oxygen saturation (SpO₂), intubation amnesia rate, patient satisfaction, and relative complications were recorded.
Results: AFOI was completed in all patients. The average total AFOI time was 14.17 ± 1.47 minutes, and the time to placing the landmark-guided bilateral superior laryngeal nerve block was 1.24 ± 0.42 minutes. The first-attempt intubation success rate was 97.5%, and patient satisfaction was 90%. Blood pressure changed (<20%) briefly after administering conscious sedation. Heart rates did not change significantly, and SpO₂ remained stable and ≥95%. Three patients had a sore throat, which resolved on postoperative day 1 without other complications. On postoperative day 1, 82.5% (33/40) of the patients had no recall of AFOI, and 17.5% (7/40) had only an indistinct memory.
Conclusions: The protocol was feasible with a high first-attempt intubation success rate and low complications rate. Hemodynamic parameters and respiration remained stable, with high patient satisfaction and effective amnesia.

Keywords
Awake fiberoptic intubation, feasibility, protocol, sedation, memory, complications

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**Introduction**

A difficult airway is a cause of severe anesthesia-related morbidity and mortality. Since the 1960s, awake fiberoptic intubation (AFOI) has been established as the gold standard for anticipated difficult tracheal intubation.\(^1\) AFOI usually requires good sedation, patient cooperation, and preserved spontaneous respiration. Drugs that can be used for AFOI sedation are opioids, benzodiazepines (midazolam), propofol, and dexmedetomidine.\(^2\)–\(^4\) Benzodiazepines combined with opioids are widely used in awake intubation because of the antegrade amnesic effect of the benzodiazepines and the analgesic effect of the opioids.\(^5\)–\(^6\) However, this combination has been reported to increase hypoxia and carbon dioxide accumulation.\(^7\) In some cases, patients can be intubated without sedation, if airway topicalization is sufficient. However, the combination of moderate conscious sedation and regional anesthesia has been more commonly used to relieve patient anxiety and to suppress the pharyngeal, laryngeal, tracheal, and bronchial reflexes during AFOI.\(^8\) Various airway topicalization techniques can be performed to facilitate AFOI; these include the superior laryngeal nerve block (SLNB),\(^9\) translaryngeal injection (TLI), and spray-as-you-go technique.\(^10\)–\(^12\)

One problem that is associated with AFOI is a long manipulation time. In addition, patients may experience strong discomfort, coughing, and resistance.\(^13\) This study aimed to evaluate the feasibility of an AFOI protocol in patients with simulated difficult intubation.

**Methods**

**Ethics**

This prospective, observational, clinical trial was approved by the Ethics Committee of Zhongshan Hospital, Fudan University (Approval No: B2017-112R) on 12 September 2017. The study was registered at clinicaltrials.gov (NCT 03343496), and written informed consent was obtained from all participants.

**Study design**

**Selection and description of the participants.** From November 2017 to January 2018, 40 patients (aged 18–75 years) who presented for elective surgery under general anesthesia and who had no history of cervical injury were recruited at Zhongshan Hospital (Fudan University, Shanghai 200032, China). The inclusion criteria were body mass index (BMI) < 28 kg/m\(^2\), American Society of Anesthesiologists (ASA) physical status I–II, and Mallampati grade I–II. The exclusion criteria were allergy to the study drugs, neck mass or infection, drug or alcohol abuse, and pregnancy.

**AFOI protocol.** The AFOI procedure was standardized for all patients (Figure 1). An anesthesiologist conducted a preanesthetic interview, during which the intubation procedures were illustrated to the patients. Informed consent was obtained before surgery. All participants received no preoperative medications. After patients arrived in the operating room, an 18-G peripheral venous catheter was placed, and oxygen (8 L/min) was supplemented via face mask. Additionally, a 20-G arterial catheter was inserted into the radial artery with local lidocaine infiltration. Intraoperative monitoring involved peripheral oxygen saturation (SpO\(_2\)), electrocardiography (lead II and V\(_5\)), heart rate, invasive blood pressure, and capnography. Cervical instability injury was simulated with a cervical support to achieve a standardized supine manipulating position.

The protocol consisted of three parts: conscious sedation, regional airway...
anesthesia, and intubation. Patients received intravenous midazolam at 0.03 mg/kg and sufentanil at 0.1 μg/kg. Then, landmark-guided bilateral superior laryngeal nerve blocks (SLNBs) consisting of 2.5 mL of 2% lidocaine per side were performed by an experienced anesthesiologist who successfully completed more than 50 AFOI and SLNB procedures. Patients were informed that topical anesthesia would be given and were asked to keep the drug in their mouths for as long as possible. Hence, 5 mL of 2% lidocaine was sprayed directly on the visible portion of the tongue using a flexible catheter with a tip to disperse the solution (MADigic Laryngo-Tracheal Mucosal Atomization Device, Teleflex Inc., Wayne, PA, USA). After 2 minutes, another 5 mL of 2% lidocaine (with air: 10 mL) was sprayed towards the subglottic region and trachea during inspiration through the working channel of the fiberoptic bronchoscope (FOB; Olympus BF Q180, Olympus Medical Systems Corp., Tokyo, Japan). After another 2 minutes, the FOB was placed below the vocal cords, and 4 mL of 2% lidocaine (with air: 10 mL) was sprayed into the trachea. Subsequently, patients were required to make two active coughs to further diffuse the lidocaine. After another 2 minutes, the fiberscope with a lubricated steel wire endotracheal tube (male patients, internal diameter (ID): 7.0 mm; female patients, ID: 6.5 mm) was introduced through the patient’s oral cavity, with the trachea opened and visualized. The tracheal rings and carina were identified, and the endotracheal tube was railroaded into the trachea. Mid-tracheal placement was confirmed.

The position of the tracheal tube was also confirmed with capnography and bilateral auscultation. General anesthesia was induced with a target-controlled infusion (TCI) of propofol at a target plasma concentration of 4 μg/mL and rocuronium at

Figure 1. Flowchart of awake fiberoptic intubation
IV, intravenous; BMI, body mass index; ASA, American Society of Anesthesiologists; ECG, electrocardiogram; SpO2, blood oxygen saturation.
0.6 mg/kg. Then, the tube was secured, and the cuff was inflated to establish mechanical ventilation.

Data collection. Baseline data were recorded before any medications were administered and after a 10-minute stabilization period. The primary outcomes were the AFOI time (defined as the time from the midazolam injection to acquiring a positive end-tidal CO₂) and the first-attempt intubation success rate.

Prespecified secondary outcomes were hemodynamic parameters (systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR)), sedation score, unexpected coughing, hypoxic episodes (SpO₂ < 90%), patient satisfaction, rate of amnesia of the intubation, vocal cord movement, and relative complications, such as arrhythmias, bleeding, hoarseness, and sore throat.

Invasive blood pressure, HR, and SpO₂ were recorded at six time points: T1: Baseline; T2: 1 minute after bilateral SLNBs; T3: 1 minute after topical anesthesia of the tongue and oropharynx; T4: 1 minute after topical anesthesia of the glottic region; T5: 1 minute after topical anesthesia of the subglottic region and trachea; and T6: 1 minute after intubation. Patient sedation was assessed using the Ramsay sedation scale. Vocal cord movement was assessed using the following scores: 1: open, 2: moving, 3: closing, and 4: closed. Unexpected coughing was evaluated with the following scores: 1: none; 2: < 3 episodes of unexpected mild coughing (comparable to “clearing one’s throat”); 3: ≥ 2 episodes of mild unexpected coughing lasting less than 1 minute; and 4: persistent unexpected coughing. The level of recall (memory of preintubation preparations, topical anesthesia, and intubation), adverse events, and patient satisfaction (1: excellent, 2: good, 3: fair, and 4: poor) were assessed during postoperative visits.

Statistics
Statistical analyses were performed with SPSS 24.0 statistical software for MAC (IBM Corp., Armonk, NY, USA), and \( P < 0.05 \) was considered statistically significant. Descriptive data (age, weight, height, AFOI time) are presented as mean ± standard deviation (SD), and categorical data (sex, secondary outcomes) are presented as frequency and percentage. Hemodynamic parameters (SBP, DBP, HR) were analyzed using the repeated measures one-way analysis of variance (ANOVA) test, and a post-hoc Bonferroni test was used for multiple comparisons.

Results
Forty patients were enrolled in the study (23 men, 17 women). All AFOI procedures were completed successfully, and the average total time was 14.17 ± 1.47 minutes. The first-attempt intubation success rate was 97.5%, and the patient satisfaction rate was 90%. All 40 patients successfully underwent bilateral SLNBs, and the time to placement was 1.24 ± 0.42 minutes. The patients’ characteristics, and primary and secondary outcomes are shown in Table 1. The vocal cords were completely open in 34 patients (85%) and moving in 6 patients (15%).

Repeated measures ANOVA revealed significant effects on SBP (\( F = 8.66, \ P < 0.05 \)) and DBP (\( F = 6.72, \ P < 0.05 \)), but not on HR (\( F = 0.77, \ P > 0.05 \)). Bonferroni correction revealed that SBP and DBP at T₂ were lower than at T₁ (\( P < 0.001 \)). However, BP fluctuations were lower than the threshold for clinical significance. Overall, hemodynamic parameters remained clinically stable during the study period. SpO₂ was stable and did not decrease below 95%.

A 73-year-old male patient had a sedation score of 5 without hypoxemia, and
another 39-year-old male patient had a sedation score of 1, which was related to his habit of taking sleeping pills, without drug abuse.

On postoperative day one, 82.5% (33/40) of the patients had no recall of the intubation process, and 17.5% (7/40) demonstrated only an indistinct memory. Three patients had a sore throat following tracheal tube removal, which resolved by postoperative day 1. No other relative complications were observed.

### Table 1. Characteristics of the patients, and primary and secondary outcomes of awake fiberoptic oral intubation (AFOI)

| Evaluated parameters                               | Awake fiberoptic intubation (n=40) |
|---------------------------------------------------|------------------------------------|
| **Characteristic**                                |                                    |
| Sex (Male/Female)                                 | 23/17                              |
| Age (years)                                       | 55.70 ± 11.20                      |
| Weight (kg)                                       | 64.25 ± 9.30                       |
| Height (cm)                                       | 165.88 ± 7.06                      |
| **Primary outcome**                               |                                    |
| AFOI time (min)                                   | 14.17 ± 1.47                       |
| **Secondary outcomes**                            |                                    |
| Level of sedation (Ramsay sedation score)         |                                    |
| 1 (anxious or restless or both)                   | 1 (2.5%)                           |
| 2 (cooperative, orientated, and tranquil)         | 28 (70%)                           |
| 3 (responding to commands)                        | 9 (22.5%)                          |
| 4 (brisk response to stimulus)                    | 1 (2.5%)                           |
| 5 (sluggish response to stimulus)                 | 1 (2.5%)                           |
| 6 (no response to stimulus)                       | 0                                  |
| Vocal cord movement                               |                                    |
| 1 (open)                                          | 34 (85%)                           |
| 2 (moving)                                        | 6 (15%)                            |
| 3 (closing)                                       | 0                                  |
| 4 (closed)                                        | 0                                  |
| Unexpected coughing during the process            |                                    |
| 1 (none)                                          | 31 (77.5%)                         |
| 2 (< 3 episodes of mild coughing)                 | 7 (17.5%)                          |
| 3 (≥ 2 episodes of mild coughing)                 | 2 (5%)                             |
| 4 (persistent coughing)                          | 0                                  |
| Patients’ satisfaction                            |                                    |
| 1 (excellent)                                     | 29 (72.5%)                         |
| 2 (good)                                          | 7 (17.5%)                          |
| 3 (fair)                                          | 3 (7.5%)                           |
| 4 (poor)                                          | 1 (2.5%)                           |

AFOI, awake fiberoptic intubation.

### Discussion

AFOI involves sedation, regional anesthesia, and intubation. Joseph et al.\(^{13}\) reviewed 1085 patients who underwent AFOI with a median procedure time of 24 minutes (interquartile range: 19–31 minutes). To our knowledge, there is currently no AFOI procedure that can ensure comfort for the patient, produce good effects, and shorten the time. Results from our study showed that our AFOI protocol was feasible and safe.
The preanesthetic interview is important for illustrating the procedure to the patient and can function to reduce patient anxiety.\textsuperscript{14} In the operating room, sedation helps maintain spontaneous respiration and effective amnesia without patient discomfort during the AFOI. Several sedatives, including midazolam, dexmedetomidine, opioids, and propofol, have been studied. Midazolam is a benzodiazepine that induces antegrade amnesia, has a faster onset of action (2–5 minutes) after intravenous administration, and the effects are typically sustained for ≥1 hour.\textsuperscript{6,15} Midazolam has been associated with respiratory depression,\textsuperscript{7} but a specific antagonist (flumazenil) can be used to quickly reverse its effect in 3 minutes.\textsuperscript{16,17} Dexmedetomidine is an alpha2-adrenergic agonist that may be used as an alternative to midazolam. The safety and efficacy of midazolam and dexmedetomidine are considered comparable regarding respiratory or hemodynamic complications. However, dexmedetomidine infusions are time-consuming because a loading dose is required over 10 minutes, followed by a maintenance dose.\textsuperscript{3,18} Additionally, dexmedetomidine does not induce antegrade amnesia. Schnack et al.\textsuperscript{19} reported that temporary discomfort was encountered frequently during awake orotracheal intubation, and only 21% of patients were able to recall the intubation when midazolam (mean dose: 1.7 mg) was used. Benzodiazepines are commonly combined with opioids (fentanyl, sufentanil) to provide analgesia, anxiolysis, amnesia, and sedation. Modak and Kane\textsuperscript{5} showed that sufentanil is superior to fentanyl regarding analgesia, patient satisfaction, and recovery, in conscious sedation. In our study, all patients received intravenous midazolam at 0.03 mg/kg and sufentanil at 0.1 μg/kg, and AFOI was completed successfully without respiratory depression. Ninety-five percent of the patients had a good Ramsay sedation score, and 82.5% had no recall of the AFOI procedure. The 39-year-old male patient with a sedation score of 1 was the only patient to report poor satisfaction, as he demonstrated an indistinct memory of the procedure and also had mild unexpected coughing. The unexpected coughing happened when the tracheal tube was passing the glottis while the vocal cord was moving. Topical anesthesia of the glottic region was re-administered, and after 1 minute, the tube passed successfully; in this case, first-attempt intubation success was not achieved.

SLNB was first described by Gaskill and Gillies in 1966\textsuperscript{20} and is frequently used to facilitate awake intubation. The superior laryngeal nerve (SLN) is a branch of the vagus nerve and is divided into internal and external branches. The internal branch provides sensory innervation to the laryngeal mucosa from the upper surface of the vocal folds to the base of the tongue. The external branch provides motor innervation to the cricothyroid muscle. Stockwell et al.\textsuperscript{9} devised a successful anatomical landmark-guided technique for SLNB, and ultrasound-guided SLNB has been used clinically, recently. However, reports of ultrasound-guided laryngeal nerve blocks are limited to case reports. Visualizing the SLN can be difficult because of its small size,\textsuperscript{21,22} and performing SLNB can be difficult and time-consuming. In this study, the time to placing landmark-guided bilateral SLNBs was 1.24 ± 0.42 minutes, with the glottis open in 85% of the patients. Because obesity can render the anatomical landmarks difficult to palpate and visualize, we enrolled only patients with normal BMI, in this study. Further studies involving obese patients are warranted.

Lidocaine is the most commonly used local anesthetic in AFOI, and several concentrations have been reported (1%, 2%, 4%, 10%). The 2% concentration provides superior intubating conditions compared
with 1%, and the 2% dose also produces lower plasma lidocaine levels compared with 4% (2.8 μg/mL vs 6.5 μg/mL, respectively). Several articles have shown that the total dose of lidocaine should be limited to 8.2 mg/kg in adults undergoing bronchoscopy. However, Williams et al. found that a maximum lidocaine dose of 9 mg/kg did not produce toxic plasma concentrations of lidocaine. In our study, we used a fixed dose of 2% lidocaine (SLNB: 100 mg, topical anesthesia: 360 mg or 5.6 mg/kg). However, we did not measure plasma lidocaine concentrations. Moreover, previous studies have demonstrated that lidocaine has a fast onset of action (1–2 minutes) that lasts <15 minutes, with a maximum analgesic effect of 4–5 minutes when applied topically to the tongue or lower lip mucosa. Thus, we selected a 2-minute interval between each step of the topical anesthesia. Hayashi et al. showed that lidocaine spray alone is similar to spray plus viscous solution for pharyngeal observation during transoral endoscopy. In our study, we used only lidocaine without viscous solution and obtained good local anesthetic effects for AFOI.

Several previous studies reported routinely administering intravenous anticholinergic drugs, such as glycopyrrolate or atropine, to reduce secretions, keep the mouth dry, and inhibit the vagus nerve response. However, anticholinergic drugs can also aggravate the symptoms of dry mouth and increase discomfort during the perioperative period. Furthermore, atropine can pass through the blood–brain barrier and cause adverse reactions, such as postoperative delirium. Therefore, no anticholinergic drugs were used in our study, and the manipulations were performed smoothly.

Different techniques have been used to topically anesthetize the airway. TLI with local anesthetics is a traditional, fast, and effective way to provide topical tracheal anesthesia. However, TLI also results in passive unexpected coughing, which is harmful to cervical stability. Walts and Kassity reported that 94% of their patients coughed, and 48% experienced severe coughing while undergoing TLI. Sethi et al. found that the total number of coughs was higher in their TLI group than in the spray-as-you-go technique group (18 vs. 12, respectively). In this study, we attempted to avoid unexpected coughing and encouraged patients to cough actively in a controlled manner, which was a very effective way to diffuse the lidocaine. TLI has also been associated with other adverse effects; tracheal or laryngeal mucosal bleeding following TLI can occur in 30% to 76% of patients. Furthermore, TLI may contaminate the surgical area if a cervical anterior approach is needed. Nebulization is another technique that is non-invasive but can be time-consuming and may be associated with more coughing.

Fiberoptic-compatible oral airways mechanically guide fiberoptic intubation and provide the simplicity and benefits that are lacking with traditional oral airways. Many different fiberoptic oral airways are available. Randell et al. found that the Ovassapian airway was superior to the Berman airway, and Greenland et al. found that the Williams airway can be used to better expose the glottis, but this advantage does not apply to difficult airways.

Conclusions
This study confirmed that our AFOI protocol was feasible. In particular, the intubation time was 14.17 ± 1.47 minutes with a high first-attempt intubation success rate (97.5%). During the intubation process, hemodynamic parameters and respiration were clinically stable, and high patient
satisfaction and effective amnesia were achieved.

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Prior presentation
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Declaration of conflicting interest
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