

Comparison of the Intubating Laryngeal Mask Airway with the Fiberoptic Intubation in Anticipated Difficult Airway Management

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Background: The intubating laryngeal mask airway (ILMA; Fastrach™; Laryngeal Mask Company, Henley-on-Thames, UK) may provide an alternative technique to fiberoptic intubation (FIB) to facilitate the management of the anticipated difficult airway. The authors therefore compared the effectiveness of the ILMA with FIB in patients with anticipated difficult intubation.

Methods: One hundred patients, with at least one difficult intubation criteria (Mallampati class III or IV, thyromental distance < 65 mm, interincisor distance < 35 mm) were enrolled (FIB group, n = 49; ILMA group, n = 51) in this prospective randomized study. Anesthesia was induced with propofol and maintained with alfentanil and propofol after an efficient mask ventilation has been demonstrated. The success of the technique (within three attempts), the number of attempts, duration of the successful attempt, and adverse events (oxygen saturation < 90%, bleeding) were recorded.

Results: The rate of successful tracheal intubation with ILMA was 94% and comparable with FIB (92%). The number of attempts and the time to succeed were not significantly different between groups. In case of failure of the first technique, the alternative technique always succeeded. Failures in FIB group were related to oxygen desaturation (oxygen saturation < 90%) and bleeding, and to previous cervical radiotherapy in the ILMA group. Adverse events occurred significantly more frequently in FIB group than in ILMA group (18 vs. 0%, $P < 0.05$).

Conclusion: The authors obtained a high success rate and comparable duration of tracheal intubation with ILMA and FIB techniques. In patients with previous cervical radiotherapy, the use of ILMA cannot be recommended. Nevertheless, the use of the ILMA was associated with fewer adverse events.

THE intubating laryngeal mask airway (ILMA; Fastrach™, Laryngeal Mask Company, Henley-on-Thames, UK) is a new device specifically designed to be an effective ventilatory device and blind intubation guide in patients with normal and abnormal airways.¹ The ILMA is designed to facilitate tracheal intubation with better insertion and intubation characteristics than the standard laryngeal mask airway (LMA).² The principal features of

the ILMA are an anatomically curved, rigid airway tube with an integral guiding handle, an epiglottic elevating bar replacing the LMA bars, and a guiding ramp to direct the tracheal tube anteriorly as it emerged from the mask aperture.²

The LMA represents a major advance in airway management³ and has been incorporated into difficult airway algorithms.^{4,5} The ILMA has been used successfully in patients with difficult airways,⁶⁻⁸ including patients in whom fiberoptic intubation (FIB) failed.⁹ Consequently, the ILMA may provide a useful alternative to FIB in difficult airway management. We therefore undertook a prospective randomized study to compare the effectiveness of the ILMA technique with FIB in patients with an anticipated difficult intubation.

Patients and Methods

This multicenter study was approved by the Local Human Subjects Committee (Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale, Pitié-Salpêtrière, Paris), and written informed consent was obtained from all patients. Adult patients with an anticipated difficult intubation undergoing scheduled surgery who required tracheal intubation with general anesthesia were prospectively included in the study. Patients were excluded if they were younger than 18 yr, had American Society of Anesthesiologists physical status IV or V, had respiratory tract pathology or coagulation disorders, required a nasal route for tracheal intubation, or were at risk of regurgitation-aspiration (previous upper gastrointestinal tract surgery, known hiatus hernia, esophageal reflux, peptic ulceration, or not fasted). Lastly, anticipated impossible intubation cases were also excluded. In accordance with the French Society of Anesthesiologists' recommendations on management of the difficult airway,⁵ these were defined as patients with a history of impossible intubation, mouth opening (interincisor distance) less than 20 mm, or cervical spine fixed in flexion. In the same manner, anticipated difficult intubation was defined in accordance with the same recommendations⁵ (except for Mallampati classification, see below) as the presence of at least one of the following: Mallampati class III or IV, thyromental distance less than 65 mm, mouth opening (interincisor distance) less than 35 mm. In addition, the Bellhouse grade III or IV¹⁰ was also collected. Mallampati classification, modified by Samsoon and Young,¹¹ was performed in the sitting position with the head in full

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extension, the tongue extended, and during phonation as previously recommended¹²; the thyromental distance was measured in sitting position with the head in extension.¹² Just before the induction of anesthesia, patients were randomly allocated to a FIB or ILMA group. Randomization was performed using a random number table in balanced blocks of 20 (10 per group). This study had a crossover design, *i.e.*, in the event of failure of the first technique, defined by three unsuccessful attempts, the alternative study method was performed. Alternative means for insuring patient oxygenation (LMA, cuffed oropharyngeal airway, and transtracheal oxygen device) were always immediately available. Before induction of anesthesia, preoxygenation was performed in all cases (4 min by bag and mask with 100% O₂). Each patient was routinely monitored during the entire procedure by electrocardiography, oxygen saturation, and end-tidal carbon dioxide tension.

The airway was topically anesthetized with 100 mg of 5% lignocaine, which was sprayed with a flexible nozzle into the posterior pharynx to decrease coughing during tracheal intubation with both techniques. Thereafter, anesthesia was induced with an intravenous injection of propofol (2 mg/kg). After demonstrating effective mask ventilation,¹³ alfentanil (12 µg/kg) was injected, and anesthesia was maintained with propofol (10 mg · kg⁻¹ · h⁻¹) as required to obtain satisfactory intubation conditions. Throughout the procedure, oxygen was administered continuously either by nasal or oral route *via* a cannula. In this study, all fiberoptic or ILMA intubations were performed by staff anesthesiologists (O. L., F. S., J. L. B., A. M., A. M. C.) experienced in both techniques and highly trained in difficult airway management techniques.

The insertion technique for the ILMA was performed as previously described¹ and consisted of a one-handed rotational movement in the sagittal plane with the head supported by a pillow to achieve a neutral position. If resistance was felt during bag ventilation or if the tracheal intubation had failed, a predetermined sequence of adjusting maneuvers was performed as previously recommended¹: (1) performing an up-down maneuver to prevent the epiglottis from down-folding, by swinging the ILMA back outward a few centimeters without deflating the cuff and then repositioning the ILMA; (2) optimizing the airway by steering the ILMA with the handle and moving it in the horizontal plane from one side to the other or raising the mask upward, while squeezing the reservoir bag to obtain the lowest resistance during insufflation and a complete expiration; and (3) removing the ILMA to change its size. Initial size selection for the ILMA was as follows: size 4 for patients less than 70 kg and size 5 for those greater than 70 kg. However, as mentioned previously, the anesthesiologist was permitted to change the size during the study, usu-

ally upward. The tracheal tube used in this study was a 7.5-mm straight-cuffed silicone tube included in the ILMA set (SEBAC, Pantin, France).

The FIB technique was performed by the attending anesthesiologist with a high priority assigned to the oral route. Nevertheless, we agreed that the nasal route could be selected when the oral route was judged very difficult. The oral approach was performed with an Ovassapian fiberoptic intubating airway.¹⁴ Moreover, to facilitate laryngeal exposure, an assistant applied a jaw thrust maneuver to maintain an open oropharyngeal space. The larynx was then sprayed with 2 ml lignocaine, 2%, through the working channel of the fiberscope, after which the tip of the fiberscope was advanced into the trachea and a second spray applied, before finally passing the tracheal tube into the trachea. When the nasal route was decided, we performed local anesthesia with 5% lignocaine naphazoline on nasal mucosa to complete the local anesthesia already performed in the oropharynx.

In both groups, correct positioning of the endotracheal tube was confirmed by detection and curve analysis of carbon dioxide in the exhaled gas and bilateral lung auscultation.

Data were collected by the attending anesthesiologist and an assistant using a data collection form, on which the following was recorded: success or failure of the technique, number of attempts, duration of the successful attempt (interval between the time of insertion of the device and the detection of end-tidal carbon dioxide), and doses of anesthetics used. Hemodynamic measurements were performed throughout the procedure. Adverse events encountered during tracheal intubation, such as oxygen desaturation (oxygen saturation < 90%), soft tissue trauma with bleeding, or bronchospasm, were also recorded.

Statistical Analysis

Data are presented as mean ± SD or median with 95% confidence interval for non-Gaussian variables. Comparison of two means was performed using the Student *t* test, and comparison of two medians was performed using the Mann-Whitney U test. Comparison of percentages was performed using the Fisher exact method. All comparisons were two-sided, and a *P* value less than 0.05 was considered significant. Statistical analysis was performed on a computer using NCSS 6.0 software (Statistical Solutions Ltd., Cork, Ireland).

An increase risk of adverse events (mainly bleeding) could be expected when the nasal route was used; therefore, we decided to perform two analyses: (1) intention to treat, including patients in whom the trachea was intubated through the nasal route; and (2) oral protocol compliance, excluding the patients in whom the nasal route was used.

Table 1. Comparison of Patients with Fiberoptic (FIB) or Intubating Laryngeal Mask Airway (ILMA) Tracheal Intubation Techniques

Group	FIB (n = 49)	ILMA (n = 51)
Height (cm)	167 ± 9	168 ± 10
Weight (kg)	74 ± 15	72 ± 18
Age (yr)	56 ± 17	55 ± 14
Male sex	28 (57)	25 (49)
Mallampati class		
I	0 (0)	0 (0)
II	1 (2)	0 (0)
III	12 (24)	13 (25)
IV	36 (73)	38 (75)
Mouth opening (mm)	37 ± 11	37 ± 10
Thyromental distance (mm)	65 ± 10	65 ± 12
Bellhouse grade		
I	4 (8)	7 (14)
II	25 (51)	28 (55)
III	10 (20)	9 (18)
IV	10 (20)	7 (14)
Propofol dose (mg)	200 (190–250)	200 (170–300)
Alfentanil dose (mg)	1.0 (1.0–1.1)	1.0 (1.0–1.0)

Data are mean ± SD, number (%), or median (95% confidence interval). No significant difference between groups. Because of rounding, adding percentages may not provide a sum of 100%.

Results

One hundred patients were included in this multicenter study, with 49 patients in the FIB group and 51 patients in the ILMA group. Patient characteristics, including age, height, weight, body mass index, sex, criteria of anticipated difficult intubation, and doses of propofol and alfentanil in both groups are shown in table 1. No significant differences were observed between groups. No hemodynamic instability was observed in either group during tracheal intubation.

Fiberoptic intubation was successful in 45 cases (92%) and ILMA was successful in 48 cases (94%) in the intention-to-treat analysis. The nasal route was performed in five patients, and no significant differences were observed between groups for the success rate according to the oral protocol compliance analysis (table 2). In addition, no significant differences were observed between groups for the number of attempts and the time to successful tracheal intubation for both types of analysis, intention to treat or oral protocol compliance (table 2).

In seven patients, the first randomly assigned method failed, four in the FIB group and three in the ILMA group. All of these patients were successfully intubated with the alternative technique, with a median time duration of 151 s and 130 s with the ILMA and FIB techniques, respectively. Successful tracheal intubation with the alternative technique was performed by ILMA on the first attempt in the four FIB technique failures and by FIB technique on the first attempt for two cases and on the second attempt for one case in the three ILMA failures. No patient had to be awakened, nor was surgery postponed. In the FIB group, reasons for failed intubations

Table 2. Comparison of Tracheal Intubation According to "Intention to Treat" or Oral Protocol Compliance

Intention to Treat	FIB (n = 49)	ILMA (n = 51)
Success	45 (92)	48 (94)
Number of attempts*		
1	32 (71)	34 (71)
2	12 (27)	10 (21)
3	1 (2)	4 (8)
Duration (s)*	110 (70–175)	87 (67–105)
Oral Protocol Compliance	FIB (n = 44)	ILMA (n = 51)
Success	41 (93)	48 (94)
Number of attempts*		
1	31 (75)	34 (71)
2	9 (22)	10 (21)
3	1 (3)	4 (8)
Duration (s)*	110 (70–175)	87 (67–105)

Data are median (95% confidence interval) or number (%). No significant differences between groups.

* Failures of the first or randomly assigned method being excluded.

were oxygen desaturation (n = 2) and bleeding with impossible glottic exposure (n = 2). In the ILMA group, failures occurred in three patients scheduled for cancer ear, nose, and throat surgery who had undergone previous cervical radiotherapy and were related to the failure to pass the tracheal tube into the trachea.

The incidence of overall adverse events and oxygen desaturation were significantly greater in FIB group compared with ILMA group, regardless of the type of analysis, intention to treat or oral protocol compliance (table 3).

Discussion

In the present study, we observed that: (1) the incidence of successful tracheal intubation with the ILMA in

Table 3. Number of Adverse Events Encountered during Fiberoptic (FIB) or Intubating Laryngeal Mask Airway (ILMA) Tracheal Intubation Techniques, According to the Analysis Used "Intention to Treat" or Oral Protocol Compliance

Intention to Treat	FIB (n = 49)	ILMA (n = 51)
SpO ₂ < 90%	5	0*
Soft tissue trauma (bleeding)	3	0
Bronchospasm	1	0
Total	9 (18)	0* (0)
Oral Protocol Compliance	FIB (n = 44)	ILMA (n = 51)
SpO ₂ < 90%	5	0*
Soft tissue trauma (bleeding)	2	0
Bronchospasm	1	0
Total	8 (18)	0* (0)

Data are number (%).

* *P* < 0.05 versus FIB.

SpO₂ = oxygen saturation measured by pulse oximetry.

patients with a difficult airway was high (94%) and comparable to FIB; (2) the number of attempts and the median time to successful tracheal intubation were not significantly different between the two methods; (3) in every case in which failure occurred with one technique, the alternative technique always succeeded. It is thus reasonable to conclude that these two tracheal intubation techniques may be considered to be equivalent and complementary, since they gave an overall success rate of 100%. In addition, adverse events (in particular oxygen desaturation) occurred significantly more frequently in the FIB group.

The efficacy of the ILMA as a ventilatory device and blind intubation guide has been previously reported in patients with normal^{1,15-18} and abnormal^{1,6-9,19,20} airways. The high success rate of blind tracheal intubation observed in our study in patients with a difficult airway is very similar to those reported in patients with normal airways.^{1,15-18} Our findings are in accordance with previous studies suggesting the potential role of ILMA as an effective ventilatory device and intubation guide in patients with a difficult airway.^{1,19,20} In addition, Brain *et al.*¹ suggested that tracheal intubation with ILMA was easier in the abnormal than in the normal airway, since the high anterior larynx associated with Cormack and Lehane grade III and IV facilitated a better alignment of the ILMA and glottic aperture. In a predominantly Chinese population in which the main airway characteristic is an anterior larynx, the value of ILMA was reported as a primary mean of establishing an airway.¹⁸ Moreover, the number of ILMA manipulations required to achieve tracheal intubation is inversely related to alignment with the larynx.²¹ This last point correlates well with our experience that when ventilation through the ILMA is easily achieved, particularly when both inspiration and expiration are smooth, the rate of successful tracheal intubation is very high, suggesting a minimal airway flow resistance and thus an optimum larynx alignment with the ILMA.

The distribution of number of attempts to achieve successful tracheal intubation with the ILMA in our study is in accordance with previous studies in patients with difficult airways, when a straight silicone tube is used.^{1,19} We used only a straight silicone tube because it seemed to have a desirable curvature for alignment with the trachea, in contrast to polyvinylchloride or standard reinforced tubes, which, because of the additional curvature imparted to them during passage through the ILMA, may emerge from the ILMA with their distal ends directed too anteriorly.² Moreover, the level of difficulty for tracheal intubation in the two groups was similar, as suggested by the overall success rate, the duration of successful tracheal intubation, and the distribution of successful attempts (table 2).

In our study, failures of intubation through the ILMA all occurred in patients with ear, nose, and throat cancer and previous cervical radiotherapy. In these patients,

optimal ventilation and alignment of the ILMA with the glottic aperture are extremely difficult to achieve because the efficacy of seal for the ILMA depends on pharyngeal mucosal pressures,²² and consequently increased leaks occurred during ventilation as well as difficulties in alignment of the mask. In addition, as previously reported with LMA,²³ the presence of the inflated mask in a narrowed hypopharynx may compress laryngeal structures in an inextensible neck, inducing a glottic collapse and making tracheal intubation more difficult. In our study, ventilation through the ILMA in these patients was not optimal for performing blind tracheal intubation, but it did prevent oxygen desaturation.

We have given a high priority to the oral route with the FIB technique to better compare the results with the ILMA. However, forbidding the nasal route would have unfavorably affected comparison of the success rate of the FIB technique with the ILMA technique. Consequently, we performed the two analyses either in "intention to treat" (keeping the patients in whom the nasal route was used) and the "oral protocol compliance" (excluding the patients in whom the nasal route was used). In our opinion, presentation of these two analyses is a pragmatic approach because the first method adheres to clinical practice without putting the FIB technique at a disadvantage by prohibiting the nasal route, and the second, by excluding the patients in whom the nasal route was used and thus the occurrence of bleeding, enables us to show differences between groups for the adverse events related to oxygen desaturation episodes.

The lack of adverse events, in particular oxygen desaturation, in the ILMA group is noteworthy. Moreover, whatever the type of analysis performed, intention to treat or oral protocol compliance, we obtained identical results either for the main end point (rate of success) or secondary end point (adverse events). The ILMA has been specifically designed to be an effective ventilatory device,¹ as has been confirmed by previous studies in patients with normal airways.¹⁵⁻¹⁸ Moreover, satisfactory ventilation with the ILMA was reported to be more common than with the face mask in adult patients undergoing elective surgery in whom difficult intubation was not anticipated.^{18,24} In anticipated difficult airway patients, the success rate of efficient ventilation was also high,^{1,19,20} and no oxygen desaturation episodes were reported in patients undergoing general anesthesia.^{1,19} In unanticipated difficult tracheal intubation, the LMA provides rescue ventilation in 94% of patients who are difficult to ventilate or intubate, compared with only 50% when a fiberoptic bronchoscope was used as an emergency airway technique for rescue ventilation in these cases.²⁵ Thus, the ILMA may potentially decrease the morbidity and mortality resulting from hypoxia or anoxia associated with a failure to achieve ventilation. It could thus be considered as an interesting option in difficult airway management, as is the LMA in difficult airway algorithms.^{4,5}

In assessing the relevance of our study, the following points should be considered. First, the power of our study was too low to demonstrate a significant difference between these techniques, because of their low failure rate. Assuming a percentage of success of FIB technique of approximately 95%, a trial ($\alpha = 0.10$, $\beta = 0.10$) sufficient to detect a 5% difference between the two techniques would include more than 1,000 patients. Because difficult intubation occurs in only 8% of our adult population,¹³ we considered that such a trial was impractical. However, our study was large enough to show some differences between these two tracheal intubation techniques. Second, this study was conducted in patients with anticipated difficult intubation during general anesthesia. The combination of propofol and alfentanil has been reported to provide satisfactory intubation conditions in outpatients for elective maxillofacial surgery, and a significant improvement of jaw relaxation and vocal cord conditions to perform successful tracheal intubation was reported with this combination in comparison with propofol alone.²⁶ Moreover, Shung *et al.*²⁰ reported that ILMA insertion in patients with a difficult airway was appropriate only in those who were well sedated without loss of consciousness. It should be noted that patients with an anticipated impossible intubation, as previously defined,⁵ or those with a difficult or impossible face mask ventilation were excluded from our study. In these patients, awake tracheal intubation is recommended.^{4,5} Therefore, our results should not be considered applicable to patients with anticipated impossible intubation or those with a difficult face mask ventilation. Further studies are needed to compare these two techniques in awake patients. Lastly, all investigators were highly trained in difficult airway management and were accustomed to performing these two tracheal intubation techniques in patients with a difficult airway. Thus, the level of investigator experience should be taken into account, and the results of our study cannot necessarily be extrapolated to patients with an unanticipated difficult airway or to anesthesiologists with differing levels of training in ILMA and FIB techniques. However, inexperienced practitioners were reported to be more successful using the ILMA than the LMA with respect to insertion success rate in cadavers.²⁷ As previously reported,¹⁵ the learning curve for blind tracheal intubation with ILMA seemed to be rapid.

In conclusion, in an adult population with an anticipated difficult airway, we obtained a high success rate of tracheal intubation both with the ILMA and FIB techniques, and comparable procedure duration was observed. Moreover, when one technique failed, the alternative method was always successful, suggesting that these two techniques may be complementary. We were not able to show one technique was more successful than the other; however, patients with ear, nose, and throat cancer and previous radiotherapy involving the

pharynx were unsuitable for the ILMA technique. Lastly, in patients with anticipated difficult airway management, the ILMA was found to be associated with less adverse events during tracheal intubation, in particular oxygen desaturation.

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