Original Research Paper

Volume-9 | Issue-2 | February-2019 | PRINT ISSN - 2249-555X

Anesthesiology

A DESCRIPTIVE STUDY ON USE OF FASTRACH INTUBATING LARYNGEAL MASK AIRWAY (ILMA) [PILOT STUDY]

Dr. Smita Joshi	Professor, Department Of Anaesthesiology, Dr. D. Y. Patil Medical College, Hospital & Research Centre, Pune.
Dr. Ankit Sawhney*	P.G. Resident, Department of Anaesthesiology, Dr. D. Y. Patil Medical College, Hospital & Research Centre, Pune. *Corresponding Author

ABSTRACT

INTRODUCTION: Intubating Laryngeal Mask Airway (ILMA) is a newer supraglottic airway device for securing an airway, not requiring direct visualisation, offering an easier approach for blind intubation and having minimal ramifications on the vital haemodynamics. The purpose of this study was to assess its overall superiority, maintenance of haemodynamic stability and any repercussions with the use of Fastrach ILMA.

METHODOLOGY: This prospective study was conducted on 30 adult patients with ASA 1 & 2 status posted for elective surgeries. Patients received balanced general anaesthesia. Tracheal intubation was done using Fastrach ILMA. The number of attempts required for successful intubation, haemodynamic changes, intubating complications & any challenges faced during the procedure were noted.

RESULTS: We were able to intubate successfully 29 out of 30 patients without any substantial hemodynamic changes as compared to their baseline.

CONCLUSIONS: In patients with normal airway, blind intubation with Fastrach ILMA is an easy and effictive method without any remarkable complications or changes to hemodynamics. ILMA can reasonably be used as a primary intubating device in patients with normal airways.

KEYWORDS : Blind intubation, Haemodynamic stability, Intubating laryngeal mask airway (ILMA)

INTRODUCTION

In 1983, use of fibre optic views of laryngeal inlet through classic LMAs, convinced Archie Brain to develop a newer Supraglottic Airway Device which could be used as a conduit for intubation as well[6]. So he developed a prototype intubating LMA that incorporated a 14mm plastic tube attatched with a Goldman cuff which allowed passage of a 9mm tracheal tube. It is a modification of the classic LMA itself such that its shape allows easy placement and alignment allows passage of an endotracheal tube to directly be slipped into the laryngeal inlet. Since then, various models of ILMA have been improvised and modified, untill 1997 when FASTRACH ILMA was introduced[4]. It has a C shaped rigid curved airway tube. A rigid handle for one handed insertion in any patient position. An air filled LMA cuff with epiglottic elevating bar. A dedicated reinforced tracheal tube with low volume high pressure cuff and a stabilizing rod to hold the tube in place while removing the LMA[3,5]. (Fig 1)

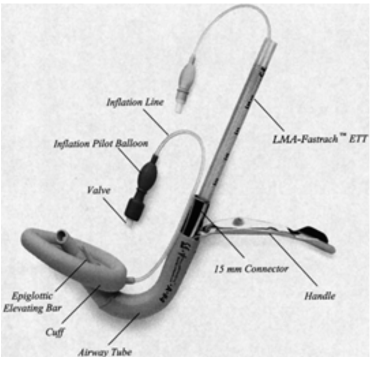


Fig 1 : Demonstration of parts of FASTRACH ILMA

Most anaesthetic deaths occur because of failure to ventilate or intubate. With the use of FASTRACH Intubating LMA, the patient can be maintained on spontaneous ventilation with or without anaesthesia and it can also be used as a channel to facilitate securing a definitive airway blindly, without direct laryngoscopy.

ILMA has been proven to be a promising tool for both aided ventilation and a fundamental airway management device in both pre hospital and dangerous challenging environments.

MATERIAL & METHODS

This pilot project was conducted in the department of Anaesthesia at Dr. D. Y. Patil Medical College, Hospital and Research centre. It was a descriptive study which was initiated in a sample of 30 patients after approval of the instituitional ethics committee. All the patients belonged to either ASA grade I or II, aged between 15 to 65 years, including either gender, posted for elective surgeries scheduled for intubation under elective general anaesthesia.

Informed written consent for the intubation procedure and publishing and broadcasting of results in both manual and digital manner was taken. Willing patients who fasted for more than 6 hours, with no associated co morbidities and having a pre assessed normal airway, were included in the study.

Pre operative evaluation was done for the routine investigations like complete blood count, serum electrolytes, blood sugar level, coagulation profile, electrocardiograph and chest x-ray.

Prior to starting the procedure, baseline values of vital parameters like Heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Mean Arterial Pressure (MAP), Oxygen saturation at room air (SpO2), Respiratory rate (RR) and any ECG changes were noted.

Patients were premedicated to their corresponding weights and were given balanced general anaesthesia using Inj. Fentanyl (1.5 mcg/kg), Inj. Propofol (2 mg/kg) followed by Inj. Suxamethonium (2 mg/kg). Patient's lungs were gently ventilated and preintubation vitals were noted again while the effect of depolarizing muscle relaxant got established.

Body weight	ILMA size	Air volume	Tracheal Tube
30-50kg	3	20ml	7mm
50-70kg	4	30ml	7.5mm
70-100kg	5	40ml	8mm

Fig 2 : Recommended ILMA size, volume of air and tracheal tube size for corresponding weight

An ILMA of appropriate size (according to the weight of the patient) was chosen (Fig 2) and dorsal surface of the bowl and the designated size armoured endotracheal tube were lubricated to ensure easy entry into the mouth and passage of the tube. Cuffs of both the LMA and the tracheal tube were checked and deflated before use.

After adequate mouth opening and head placed in neutral position, ILMA is held by the handle which is parallel to the chest. The tip of the mask is positioned posterior to the upper incisors and slid back & forth over the palate to distribute the lubricant. ILMA was inserted into the oral cavity approximated to the hard palate and posterior pharyngeal wall, rotating the steel handle along the axis of the LMA. Cuff of the LMA was inflated with air (amount depending on the size of ILMA) and Bain's circuit was attatched to the universal connector of the LMA. Bilateral air entry was confirmed by chest rise, auscultation and capnography on gentle manual ventilation.

Inhalational anaesthesia with Nitrous oxide and sevoflurane with oxygen were started and vital parameters were noted again at this point. Upon confirmation of good and adequate ventilation, the armoured tracheal tube was passed through the stem of ILMA followed by use of stabilizing rod to hold it in place and remove the LMA by sliding it over the tube as the tube appeared in the bowl of the LMA and was secured. Bilateral air entry was reconfirmed and hemodynamic readings were noted after the tube was fixed and patient put on controlled ventilator settings.

Number of attempts to intubate, ease of intubation calliberated on a likert scale, success in securing the airway and feedback from the operator were documented.

STATISTICAL ANALYSIS

The quantitative data was collected, compiled and tabulated. Statistical analysis was done using ANOVA test and pair wise comparison using Post Hoc test with 95% confidence value.

OBSERVATION AND RESULTS

Tables 1a & 1b: Heart Rate (HR)

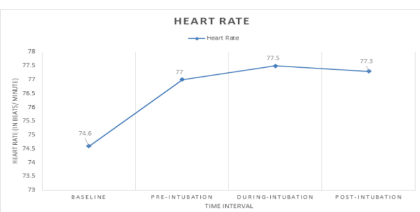
Interval	Mean	df	F Value	P Value
Baseline	74.60 ± 8.73	2.343	5.462	**.004**
Pre-intubation	77.00 ± 9.80			
During-Intubation	77.50 ± 8.77			
Post-intubation	77.30 ±10.80			

Test Applied: Repeated Measure ANOVA

Reference Interval (I)	Comparison Interval (J)	Mean Difference (I-J)	Std. Error	95% Confidence Interval for Difference		P Value
				Lower Bound	Upper Bound	
Baseline	Pre-Intubation	-2.400*	.864	-4.167	-.633	**.009**
	During-Intubation	-2.900*	.682	-4.295	-1.505	**<.001**
	Post-Intubation	-2.700*	1.044	-4.835	-.565	**.015**
Pre-Intubation	During-Intubation	-.500	.660	-1.851	.851	**.455**
	Post-Intubation	-.300	.898	-2.138	1.538	**.741**
During-Intubation	Post-Intubation	.200	.674	-1.178	1.578	**.769**

Test Applied: Pair Wise Comparison Using Post Hoc

Graph 1: Line diagram showing the trend of changes in Heart Rate



Tables 2a & 2b: Systolic Blood Pressure (SBP)

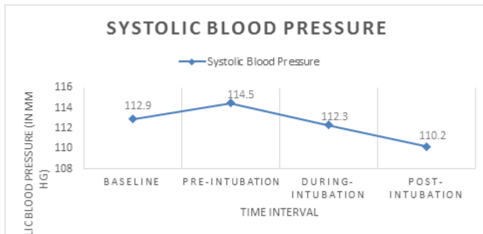
Interval	Mean	df	F Value	P Value
Baseline	112.90 ± 8.67	1.596	3.211	**.060**
Pre-intubation	114.50 ± 9.59			
During-Intubation	112.30 ± 11.16			
Post-intubation	110.20 ± 9.95			

Test Applied: Repeated Measure ANOVA

Reference Interval (I)	Comparison Interval (J)	Mean Difference (I-J)	Std. Error	95% Confidence Interval for Difference		P Value
				Lower Bound	Upper Bound	
Baseline	Pre-Intubation	-1.600	.623	-2.873	-.327	**.016**
	During-Intubation	.600	1.672	-2.819	4.019	**.722**
	Post-Intubation	2.700	1.810	-1.002	6.402	**.147**
Pre-Intubation	During-Intubation	2.200	1.289	-.436	4.836	**.098**
	Post-Intubation	4.300	1.591	1.046	7.554	**.011**
During-Intubation	Post-Intubation	2.100	1.081	-.111	4.311	**.062**

Test Applied: Pair Wise Comparison Using Post Hoc

Graph 2: Line diagram showing the trend of changes in SBP



Tables 3a & 3b: Diastolic Blood Pressure (DBP)

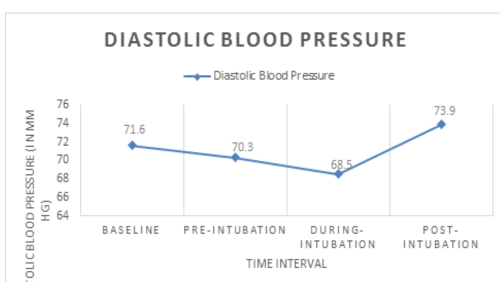
Interval	Mean	df	F Value	P Value
Baseline	71.60 ± 5.97	1.993	4.305	.129
Pre-intubation	70.30 ± 7.76			
During-Intubation	68.50 ± 7.49			
Post-intubation	73.90 ± 9.68			

Test Applied: Repeated Measure ANOVA

Reference Interval (I)	Comparison Interval (J)	Mean Difference (I-J)	Std. Error	95% Confidence Interval for Difference		P Value
				Lower Bound	Upper Bound	
Baseline	Pre-Intubation	1.300	.818	-.373	2.973	**.123**
	During-Intubation	3.100	1.398	.240	5.960	**.035**
	Post-Intubation	-2.300	1.879	-6.143	1.543	**.231**
Pre-Intubation	During-Intubation	1.800	1.114	-.477	4.077	**.117**
	Post-Intubation	-3.600	1.885	-7.455	.255	**.066**
During-Intubation	Post-Intubation	-5.400	1.855	-9.195	-1.605	**.007**

Test Applied: Pair Wise Comparison Using Post Hoc

Graph 3: Line diagram showing the trend of changes in DBP



Tables 4a & 4b: Mean Arterial Pressure (MAP)

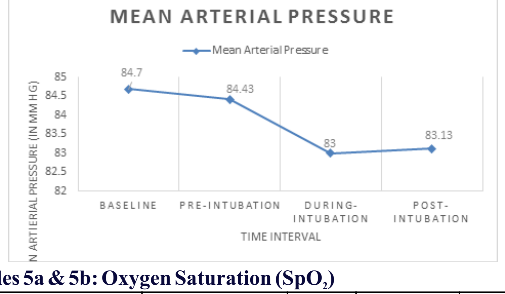
Interval	Mean	df	F Value	P Value
Baseline	84.70 ± 6.19	1.672	1.301	**.278**
Pre-intubation	84.43 ± 8.03			
During-Intubation	83.00 ± 8.30			
Post-intubation	83.13 ± 4.51			

Test Applied: Repeated Measure ANOVA

Reference Interval (I)	Comparison Interval (J)	Mean Difference (I-J)	Std. Error	95% Confidence Interval for Difference		P Value
				Lower Bound	Upper Bound	
Baseline	Pre-Intubation	.270	.624	-1.005	1.545	**.668**
	During-Intubation	1.700	1.405	-1.173	4.573	**.236**
	Post-Intubation	1.570	1.165	-.813	3.953	**.188**
Pre-Intubation	During-Intubation	1.430	1.138	-.896	3.756	**.219**
	Post-Intubation	1.300	1.206	-1.167	3.767	**.290**
During-Intubation	Post-Intubation	-.130	.767	-1.698	1.438	**.867**

Test Applied: Pair Wise Comparison Using Post Hoc

Graph 4: Line diagram showing the trend of changes in MAP



Tables 5a & 5b: Oxygen Saturation (SpO_2)

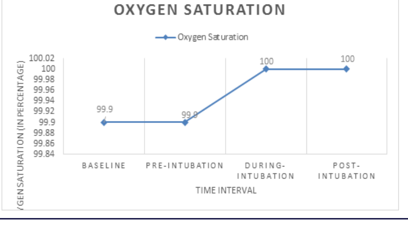
Interval	Mean	df	F Value	P Value
Baseline	99.90 ± 0.30	1.000	3.222	**.083**
Pre-intubation	99.90 ± 0.30			
During-Intubation	100.00 ± 0.00			
Post-intubation	100.00 ± 0.00			

Test Applied: Repeated Measure ANOVA

Reference Interval (I)	Comparison Interval (J)	Mean Difference (I-J)	Std. Error	95% Confidence Interval for Difference		P Value
				Lower Bound	Upper Bound	
Baseline	**Pre-Intubation**	.000	.000	.000	.000	-
	During-Intubation	-.100	.056	-.214	.014	**.083**
	Post-Intubation	-.100	.056	-.214	.014	**.083**
Pre-Intubation	**During-Intubation**	-.100	.056	-.214	.014	**.083**
	Post-Intubation	-.100	.056	-.214	.014	**.083**
During-Intubation	**Post-Intubation**	.000	.000	.000	.000	-

Test Applied: Pair Wise Comparison Using Post Hoc

Graph 5: Line diagram showing the trend of changes in SpO[2]



There were no abnormal changes seen in the electrocardiograph in any of the patients during the procedure and there was no abnormal increase or decrease in the respiratory rate of any patient except when they were asked to breathe deep during preoxygenation.

All the tracheal intubations were done successfully in a single attempt except for one esophageal (unsuccessful) intubation that occurred because of use of inappropriate size of the ILMA corresponding to the weight of that patient.

On the LIKERT scale **Very Easy / Easy / Not much difference / Difficult / Very difficult;** all the users responded to the procedure as **Easy or Very easy**.

DISCUSSION

Laryngoscopy produces stimulation of mechanoreceptors present over the pharyngeal wall, epiglottis and supraglottic area thereby triggering the sympathetic nervous system to produce adrenergic stress response. Even though this is a natural response of the body, it may be life threatening to patients who have compromised cardiovascular or respiratory diseases[1].

Also in some patients anesthetists face a “Can't intubate, Can't Ventilate” or a “Can Ventilate, Can't Intubate” type of situation. So securing a patent airway and ability to ventilate with adequate gas exchange is a crucial and mandatory measure before subjecting a patient to general anesthesia.

FASTRACH ILMA is an advanced supraglottic airway device which has shown promising results to attenuate this stress response of laryngoscopy by totally eliminating its need in the entire process of tracheal intubation[2].

The procedure for securing ILMA into the patients supraglottic region generates a reasonable low pressor response as has been analysed from the statistical data obtained from 30 patients in our pilot study.

The parameters were compared not just during the baseline, pre intubation, during intubation and post intubation values but also in pairs to successive timings using Post Hoc test.

Mean of **Heart Rate (as shown in table 1a & 1b)** during the baseline (74.60 ± 8.73) was comparable to pre intubation (77.0 ± 9.80), during intubation (77.50 ± 8.77) and post intubation (77.30 ± 10.80) values. The p value was 0.004 which shows that changes in heart rate during the procedure were significant for this pilot study and the heart rate was maintained between 74 to 78 beats per minute during the entire procedure. It increased minimally during intubation and showed a decreasing trend towards baseline post extubation.

Mean of **Systolic blood pressure (as shown in table 2a & 2b)** during the baseline (112.90 ± 8.67) was comparable to pre intubation (114.50 ± 9.59), during intubation (112.30 ± 11.16) and post intubation (110.20 ± 9.95) values. The p value was 0.060 which shows that changes in SBP during the procedure were not significant for this pilot study and the SBP range was maintained between 110 & 114 mm of Hg during the procedure. It increased mildly at the time of premedication but showed a decreasing trend towards baseline during and after intubation indicating minimal triggering of pressor response by the procedure.

Mean of **Diastolic blood pressure (as shown in table 3a & 3b)** during the baseline (71.60 ± 5.97) was comparable to pre intubation (70.30 ± 7.76), during intubation (68.50 ± 7.49) and post intubation (73.90 ± 9.68) values. The p value was 0.129 which shows that changes in SBP during the procedure were not significant for this pilot study and the DBP range was maintained between 68 & 74 mm of Hg during the procedure. It shows a small decreasing trend till the time of intubation which is picked up immediately at the end of procedure.

Mean of **Mean Arterial blood pressure (as shown in table 4a & 4b)** during the baseline (84.70 ± 6.19) was comparable to pre intubation (84.43 ± 8.03), during intubation (83.00 ± 8.30) and post intubation (83.13 ± 4.51) values. The p value was 0.278 which shows that changes in MAP during the procedure were not significant for this pilot study and the MAP range was strictly maintained between 83 & 85 mm of Hg during the procedure. It shows a similar trend as DBP and tight control reflects the essence and superiority of this supra glottis airway device.

Mean of **Oxygen saturation (as shown in table 5a & 5b)** during the baseline (99.90 ± 0.03), pre intubation (99.90 ± 0.30), during intubation (100.00 ± 0.00) and post intubation (100.00 ± 0.00) values. The p value was 0.083 which shows that changes in SaO_2 during the procedure were not significant for this pilot study and the SpO_2 was maintained above 99% throughout the procedure.

29 out of 30 patients were intubated successfully using ILMA with a single attempt even by a first time user. The one and only failed intubation happened because of an inappropriate (larger) size of ILMA used for that patient as the patient was overweight and the size corresponding to this weight had a larger bowl because of which the tracheal tube slipped from the improperly sealed laryngeal inlet into the esophagus.

Subjective analysis of the ease of intubation on Likert scale collectively concluded the procedure being easy or very easy. Nevertheless the success rate of intubation using FASTRACH ILMA was 96.67% in our pilot study.

Based on the feedback received from the users, we were able to collectively document certain advantages and drawbacks of Fastrach ILMA.

Advantages included, a) Skillful direct laryngoscopy not required, b) Comparitively easier to use and intubate than with other supra glottic airway devices, c) minimal hemodynamic changes during the procedure, d) Does not pose any difficulty in patients with loose teeth, caps or artificial dentures.

Drawbacks included, a) Passing armoured endotracheal tube through the ILMA was difficult for a beginner, b) Difficulty in passing suction catheter through the armoured endotracheal tube, c) High pressure and low volume cuff, so not recommended for long duration surgeries, d) Weight wise use of recommended ILMA size may not always fit correctly for the patient. Clinical judgement is essential, e) Time lag in intubation process due to length of the procedure, f) ILMA cannot be used in an MRI unit.

CONCLUSION
No laryngoscopy required and no manipulation of head needed are strong advantages that render FASTRACH ILMA superiority over other supraglottic airway devices and also make it a rational alternative to primary intubating devices for blind endotracheal intubation in patients with normal airway.

ACKNOWLEDGEMENT
I am very thankful to my P.G. guide Dr. Smita Joshi (Professor) for her constant support and esteemed guidance and Dr. D. Y. Patil Vidyapeeth University, Pune, for funding this research project.

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