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Original Research Article

A Randomized Control Study to Compare Hemodynamic Responses Between the Direct Laryngoscopy and the Intubating Laryngeal Mask Airway at the Tertiary Care Centre

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Abstract:

Background: Direct laryngoscopy with the Macintosh laryngoscope is the standard technique for endotracheal intubation during general anaesthesia. However, laryngoscopy and intubation can provoke sympathetic stimulation leading to tachycardia and hypertension. The Intubating Laryngeal Mask Airway (ILMA) is an alternative airway device that allows ventilation and blind tracheal intubation without direct laryngoscopy.

Objective: To compare the hemodynamic responses and intubation characteristics of tracheal intubation using direct laryngoscopy and ILMA in patients undergoing elective surgery under general anaesthesia.

Methods: This prospective randomized comparative study included 110 adult patients aged 18–65 years with ASA physical status I–II scheduled for elective surgery under general anaesthesia. Patients were randomly divided into two groups of 55 each: Group M underwent intubation using direct laryngoscopy with Macintosh blade, and Group I underwent intubation using ILMA. Hemodynamic parameters including heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure were recorded at baseline, before intubation, during intubation, and at 1, 2, 5, and 10 minutes after intubation. Intubation time, success rate, and complications were also assessed.

Results: The mean intubation time was significantly shorter in Group M compared with Group I ($p < 0.05$). The first-attempt success rate was higher in Group M, although the overall success rate was 100% in both groups. Hemodynamic parameters showed transient increases during intubation in both groups without significant differences.

Conclusion: Direct laryngoscopy provides faster tracheal intubation with a higher first-attempt success rate, while ILMA offers comparable hemodynamic stability and can be considered a feasible alternative airway device.

Keywords: Direct laryngoscopy, Endotracheal intubation, Hemodynamic response, Intubating laryngeal mask airway, Macintosh laryngoscope.

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Introduction

Airway management is a fundamental skill in anaesthesiology, resuscitation, critical care, and emergency medicine. The anaesthesiologist is primarily responsible for maintaining and securing the airway of patients undergoing surgical procedures. Endotracheal intubation is commonly performed via the orotracheal route using a laryngoscope. This technique isolates the respiratory tract from the digestive tract, allows control of ventilation, and facilitates the administration of oxygen, anaesthetic gases, and drugs.

However, laryngoscopy and endotracheal intubation are among the most invasive stimuli during anaesthesia. The pressor response to laryngoscopy is a sympathetic reflex caused by stimulation of the oropharyngeal and laryngeal structures, resulting in tachycardia, hypertension, and increased release of catecholamines [1]. Although these hemodynamic changes are usually transient, they may be exaggerated and potentially harmful in patients with hypertension, recent myocardial infarction, or cerebrovascular disease. Therefore, reducing the hemodynamic stress response associated with intubation is an important consideration during anaesthetic management.

The laryngeal mask airway (LMA), developed by Dr. Archie Brain between 1981 and 1987, combines the advantages of a non-invasive face mask and a more invasive tracheal tube, thereby filling an important gap in airway management techniques [2]. The Intubating Laryngeal Mask Airway (ILMA) is a modification of the LMA designed to facilitate ventilation as well as blind tracheal intubation without the need for direct laryngoscopy [3]. It also reduces cervical spine movement and may produce fewer cardiovascular responses compared with conventional laryngoscopy.

However, previous studies have reported conflicting results regarding the hemodynamic responses during endotracheal intubation performed using ILMA compared with direct laryngoscopy. Therefore, the present study was undertaken to compare the hemodynamic responses associated with tracheal intubation using direct laryngoscopy and ILMA. Hemodynamic parameters including systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) were recorded at baseline, before intubation, during intubation, and at 1, 2, 5, and 10 minutes after intubation in patients undergoing general anaesthesia.

Methodology

This prospective, randomized, comparative study was designed to evaluate the hemodynamic responses and intubation characteristics of tracheal intubation using an Intubating Laryngeal Mask Airway (ILMA) versus conventional direct laryngoscopy with a Macintosh blade in adult patients undergoing elective surgery under general anaesthesia.

Study design and site

- Study type: Prospective, randomized, comparative clinical study.
- Study setting: Tertiary care center operating rooms equipped for general anaesthesia and advanced airway management.
- Study period: July 2022 to January 2024.

Study population and sampling

The study included 110 adult patients fulfilling predefined eligibility criteria.

- Sample size: 110 patients.
- Group I (n = 55): Intubation via Intubating Laryngeal Mask Airway (ILMA).
- Group M (n = 55): Intubation via Direct laryngoscopy using Macintosh blade.

Inclusion criteria

- ASA physical status I–II.
- Age 18–65 years of either sex.
- Scheduled for elective surgery under general anaesthesia requiring endotracheal intubation.
- Inter-incisor distance >5 cm.
- Modified Mallampati class I–II.
- Thyromental distance ≥6.5 cm.
- Neck circumference:
  - <38 cm in men,
  - <35 cm in women.
- Free neck mobility.

Exclusion criteria

- ASA physical status III–IV.
- Emergency intubations.
- Inter-incisor distance <5 cm.
- Modified Mallampati class III–IV.
- Thyromental distance <6.5 cm.
- Neck circumference:
  - 38 cm in men,
  - 35 cm in women.
- Restricted neck mobility or rigid neck.
- Age <18 or >65 years.
- Patients in whom adequate mask ventilation was not possible.
- Patients requiring more than two intubation attempts.

Preoperative assessment and preparation

Preoperative evaluation was conducted one day before surgery.

- Detailed history: past, personal and family history.
- General physical examination.
- Baseline vitals: heart rate, blood pressure, SpO_2.
- Airway assessment: Mallampati class, inter-incisor distance, thyromental distance, neck movements, neck circumference.
- Relevant investigations as per institutional protocol.
- Fasting: patients were kept nil per os for 8 hours preoperatively.
- Written informed consent obtained after explaining the procedure and study purpose.

Operating room preparation

- Functional anaesthesia machine with:
  - Macintosh laryngoscopes, ILMA (sizes 3 or 4), face masks, oral/nasal airways.
  - Endotracheal tubes (7.0–7.5 mm for females, 8.0–8.5 mm for males), stylet, elastic bougie.
- Suction apparatus.
- Drugs for induction, maintenance and resuscitation.

- Monitoring: multiparameter monitor with ECG, non-invasive blood pressure, pulse-oximetry, and capnography.

Anaesthetic technique

Premedication

All patients received the following intravenous premedication:

- Glycopyrrolate 4 µg/kg.
- Ondansetron 0.15 mg/kg.
- Midazolam 0.02 mg/kg.
- Fentanyl 2 µg/kg.

Induction and muscle relaxation

- Pre-oxygenation with 100% oxygen for 3 minutes.
- Induction with Propofol 2 mg/kg IV.
- After confirming effective mask ventilation, Atracurium 0.5 mg/kg IV was administered.

Patients in whom mask ventilation was difficult or inadequate were excluded from the study at this stage.

Airway management techniques

Group M – Direct laryngoscopy (Macintosh)

- Patient positioned in sniffing position.
- Direct laryngoscopy performed using Macintosh laryngoscope.
- Endotracheal tube advanced under direct vision through the vocal cords.
- Manoeuvres required were noted, such as:
    - External laryngeal manipulation.
    - Use of stylet.
    - Use of bougie.
- Maximum two attempts allowed; beyond this, the patient was managed as per clinical need and excluded from analysis.

Group I – Intubating Laryngeal Mask Airway

- Patient kept in supine position with neutral head position.
- An appropriate size ILMA (3 or 4) was inserted.
- Cuff inflated with up to 30 mL of air.
- Correct placement confirmed by:
    - Bilateral equal chest rise.
    - Equal bilateral air entry on auscultation.
    - Square-wave capnography.
    - Absence of oropharyngeal leak at peak airway pressure ≥20 cm H_2O.
- A lubricated, specially designed silicone wire-reinforced endotracheal tube was advanced through the ILMA:
    - Tube inserted until the depth marker reached the handle of the ILMA.
    - Then advanced gently until no resistance was felt and appropriate depth achieved.
    - Cuff inflated and breathing circuit connected.
    - ILMA removed over a stabilizing rod after confirmation of smooth ventilation and continuous $EtCO_2$ tracing.
- If resistance was encountered, maneuvers such as twisting of the tube and Chandy's maneuver were used; this constituted a second attempt.
- If intubation failed after two attempts, ILMA intubation was abandoned and tracheal intubation was performed with direct laryngoscopy; such cases were excluded from outcome analysis.

Outcome measurements

Time to intubation (ease of intubation)

- In Group M: time measured from insertion of the laryngoscope blade into the mouth until the appearance of a square-wave capnograph and bilateral chest movement on manual ventilation.
- In Group I: total time included insertion of ILMA, intubation through ILMA and removal of ILMA, up to confirmation with capnography and chest movement.

Hemodynamic monitoring

The following parameters were recorded:

- Heart rate (beats/min).
- Systolic, diastolic and mean arterial blood pressure (mmHg).
- SpO_2 (%).
- $EtCO_2$ (mmHg).

These were measured at:

- Baseline (before induction).
- Just before laryngoscopy/ILMA insertion.
- During endotracheal tube insertion.
- After intubation: at 1, 2, 5 and 10 minutes.

Complications

The following complications related to airway instrumentation were documented:

- Soft tissue injury (lips, tongue, oropharynx).
- Dental trauma.
- Sore throat.
- Hoarseness of voice.

Postoperative complications related to the intubation technique were recorded, while extubating details per se were not part of the study endpoints.

Data Collection: Data were collected using a structured data collection sheet. Demographic details of the patients including age, sex, weight, and ASA physical status were recorded preoperatively. Baseline hemodynamic parameters including heart

rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) were noted before induction of anaesthesia. Patients were then intubated either by direct laryngoscopy using a Macintosh laryngoscope (Group M) or through an Intubating Laryngeal Mask Airway (Group I). Hemodynamic parameters were recorded at predefined intervals: before intubation, during intubation, and at 1, 2, 5, and 10 minutes after intubation. Intubation characteristics such as time taken for intubation, number of attempts, success rate, and any complications including mucosal trauma, sore throat, hoarseness, dental trauma, or stridor were also documented. All observations were recorded by the investigator using a standardized data recording format.

Statistical Analysis

- Data were compiled and analysed using appropriate statistical software.
- Continuous variables were expressed as mean ± standard deviation.
- Group comparisons were performed using:
    - Unpaired t-test for continuous variables.
    - One-way ANOVA (single-factor) where applicable.
- A p-value ≤0.05 was considered statistically significant for all tests.

Ethical considerations: The study protocol was reviewed and approved by the Institutional Ethics Committee, and conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants after explaining the anaesthetic technique, study purpose, risks and benefits in understandable language. Confidentiality of patient data was maintained by de-identification and restricted access. No additional intervention beyond standard clinical practice was introduced, and patient safety remained the primary ethical priority.

Results

Table 1: Baseline Demographic and Airway Characteristics

Parameter	Group M (n=55)	Group I (n=55)	P value
Age (years)	36.23 ± 12.85	37.45 ± 11.30	>0.05
Gender			
Male	21 (38%)	20 (36%)	>0.05
Female	34 (62%)	35 (64%)	
ASA Grade			>0.05
Grade I	37 (67%)	33 (60%)	
Grade II	18 (33%)	22 (40%)	
Mallampati Grade			>0.05
Grade I	16	19	
Grade II	39	36	
Mouth Opening			>0.05
4 finger breadth	12	13	
3 finger breadth	43	42	
Thyromental distance (cm)	6.66 ± 0.10	6.65 ± 0.11	>0.05

Baseline demographic and airway characteristics of the patients are shown in Table 1. A total of 110 patients were included, with 55 patients in each group. The mean age was 36.23 ± 12.85 years in Group M and 37.45 ± 11.30 years in Group I, with no statistically significant difference ($p > 0.05$).

In Group M, 21 (38%) patients were male and 34 (62%) were female, while in Group I 20 (36%) were male and 35 (64%) were female, showing comparable gender distribution. Regarding ASA physical status, 37 (67%) patients in Group M and 33 (60%) in Group I were ASA Grade I, whereas 18 (33%) in Group M and 22 (40%) in Group I were ASA Grade II.

Airway assessment parameters including Mallampati grade, mouth opening, and thyromental distance were also comparable between the two groups, with no statistically significant difference ($p > 0.05$). Overall, both groups were demographically and clinically comparable at baseline.

Table 2: Comparison of Mean Pulse Rate (beats/min)

Time Interval	Group M	Group I	P value
Before induction	83.71 ± 10.66	83.02 ± 11.65	0.75
Before laryngoscopy/ILMA	80.94 ± 10.85	80.67 ± 11.93	0.90
During intubation	88.92 ± 10.53	91.22 ± 11.75	0.28
1 min after intubation	87.96 ± 10.69	91.25 ± 11.63	0.12
2 min after intubation	84.38 ± 10.60	87.76 ± 11.44	0.11
5 min after intubation	79.80 ± 10.45	83.72 ± 11.37	0.06
10 min after intubation	77.92 ± 9.97	79.60 ± 11.30	0.41

The comparison of mean pulse rate at different time intervals between the two groups is shown in Table 2. The baseline pulse rate before induction was 83.71 ± 10.66 beats/min in Group M and 83.02 ± 11.65 beats/min in Group I, with no statistically significant difference ($p = 0.75$).

During endotracheal intubation, an increase in pulse rate was observed in both groups, measuring 88.92 ± 10.53 beats/min in Group M and 91.22 ± 11.75 beats/min in Group I. The pulse rate gradually decreased over time and approached baseline values by 10 minutes after intubation in both groups.

At all measured time intervals, the differences in mean pulse rate between the two groups were statistically insignificant ($p > 0.05$).

Table 3: Comparison of Hemodynamic Parameters (Blood Pressure)

Parameter	Time Interval	Group M (Mean ± SD)	Group I (Mean ± SD)	P value
SBP (mmHg)	Before induction	121.27 ± 9.52	123.38 ± 11.04	0.23
	Before laryngoscopy / ILMA	116.43 ± 9.09	120.00 ± 11.53	0.07
	During intubation	124.98 ± 8.28	128.00 ± 10.50	0.10
	1 min	124.65 ± 8.01	127.01 ± 10.34	0.18
	2 min	120.87 ± 8.01	123.60 ± 10.23	0.12
	5 min	116.58 ± 8.08	119.63 ± 10.36	0.08
	10 min	114.87 ± 8.03	116.32 ± 10.34	0.41
DBP (mmHg)	Before induction	79.70 ± 7.26	80.47 ± 7.64	0.66
	During intubation	82.76 ± 6.53	83.52 ± 6.98	0.55
	10 min	73.16 ± 6.64	73.92 ± 7.51	0.57
MAP (mmHg)	Before induction	93.56 ± 7.50	94.77 ± 8.14	0.38
	During intubation	96.83 ± 6.60	98.19 ± 7.57	0.32
	10 min	87.06 ± 6.57	88.06 ± 7.90	0.47

The comparison of hemodynamic parameters (systolic, diastolic, and mean arterial blood pressure) between the two groups is presented in Table 3. The baseline systolic blood pressure (SBP) before induction was 121.27 ± 9.52 mmHg in Group M and 123.38 ± 11.04 mmHg in Group I, with no statistically significant difference ($p = 0.23$). During intubation, SBP increased in both groups (124.98 ± 8.28 mmHg in Group M and 128.00 ± 10.50 mmHg in Group I) and gradually decreased towards baseline values over the subsequent 10 minutes. However, the differences between the groups at all time intervals were statistically insignificant ($p > 0.05$).

Similarly, diastolic blood pressure (DBP) increased slightly during intubation in both groups (82.76 ± 6.53 mmHg in Group M and 83.52 ± 6.98 mmHg in Group I) and decreased by 10 minutes after intubation. The mean arterial pressure (MAP) also showed a similar pattern, with a mild increase during intubation (96.83 ± 6.60 mmHg in Group M and 98.19 ± 7.57 mmHg in Group I) followed by gradual normalization.

Overall, no statistically significant differences were observed in SBP, DBP, or MAP between the two groups at any measured time interval ($p > 0.05$).

Table 4: Intubation Characteristics and Complications

Parameter	Group M	Group I	P value
Intubation time (seconds)	18.56 ± 2.78	47.87 ± 4.15	<0.05
First attempt success	51 (92.73%)	46 (83.64%)	
Second attempt success	4 (7.27%)	9 (16.36%)	
Overall success rate	100%	100%	
Mucosal trauma	1 (1.8%)	3 (5.4%)	
Hoarseness	2 (3.6%)	5 (9.0%)	
Sore throat	1 (1.8%)	2 (3.6%)	
Dental trauma	0	0	
Stridor	0	0	

The intubation characteristics and associated complications were compared between Group M and Group I. The mean intubation time was significantly shorter in Group M (18.56 ± 2.78 seconds) compared to Group I (47.87 ± 4.15 seconds), and the difference was statistically significant ($p < 0.05$). The first-attempt success rate was higher in Group M, with 51 patients (92.73%) successfully intubated on the first attempt compared to 46 patients (83.64%) in Group I. A second attempt was required in 4 patients (7.27%) in Group M and 9 patients (16.36%) in Group I. However, the overall success rate of intubation was 100% in both groups.

Regarding complications, mucosal trauma occurred in 1 patient (1.8%) in Group M and 3 patients (5.4%) in Group I. Hoarseness was observed in 2 patients (3.6%) in Group M and 5 patients (9.0%) in Group I. Sore throat occurred in 1 patient (1.8%) in Group M and 2 patients (3.6%) in Group I. No cases of dental trauma or stridor were reported in either group. Overall, complications were slightly more frequent in Group I, although the incidence remained low in both groups.

Discussion:

The mean time taken for intubation in the ILMA group was 47.87±4.15 seconds, whereas the time required in the direct laryngoscopy group was 18.56±2.78 seconds, which was significantly shorter. These findings suggest that intubation using a Macintosh laryngoscope is faster compared to ILMA-guided intubation. The results of our study are comparable with those reported in other studies [4].

A similar study conducted by Waltl [5] compared the time required for endotracheal intubation between ILMA and direct laryngoscopy groups and reported findings consistent with the present study. They concluded that in the absence of anticipated intubation difficulty, direct laryngoscopy remains the fastest technique for securing the airway. The longer time required for ILMA-guided intubation can be explained by the multiple steps involved in the procedure, including insertion of the ILMA, confirmation of its correct placement, passage of the endotracheal tube through the device, and finally removal of the ILMA. Additionally, the relatively longer duration may also be attributed to limited operator experience with the ILMA compared with conventional laryngoscopy.

In the present study, the first-attempt success rate for ILMA-guided intubation was 83.64%, which was lower compared to 92.73% observed in the direct laryngoscopy group. However, the overall success rate of intubation was 100% in both groups.

In the present study, heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure decreased from baseline following premedication and induction with propofol in both groups. However, during endotracheal intubation and within the first two minutes after intubation, both groups showed a transient increase in heart rate and blood pressure compared to baseline values.

Despite these changes, the differences between the two groups were not statistically significant ($P>0.05$) at any time interval. These findings suggest that ILMA-guided intubation does not provide a significant advantage over direct laryngoscopy in attenuating the hemodynamic stress response during intubation in normotensive patients.

The findings of the present study are consistent with the observations reported by Kihara and colleagues [6], who found no significant differences in hemodynamic variables such as heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure between ILMA and direct laryngoscopy groups. They suggested that ILMA and other alternative intubation techniques may attenuate the hemodynamic response in hypertensive patients but not significantly in normotensive individuals. Since our study included only normotensive patients, the results are comparable with their findings.

Choyce and associates [7] evaluated the pressor response to intubation by measuring plasma catecholamine levels along with heart rate and blood pressure. Their study demonstrated that the magnitude of pressor response during intubation was similar whether intubation was performed using direct laryngoscopy or blindly through an ILMA. Furthermore, they observed that delayed removal of the ILMA did not reduce the initial pressor response

and instead was associated with a second pressor response.

Similarly, Kihara et al. [8] evaluated the hemodynamic response during intubation through an ILMA in 120 patients without cardiovascular disease and found no significant increase in systolic or diastolic blood pressure, although a transient increase in heart rate was observed one minute after insertion of the ILMA.

Sener et al. (2012) [9] compared the hemodynamic effects of intubation using direct laryngoscopy and LMA-Fastrach in hypertensive patients. They reported no significant difference in hemodynamic responses between the two techniques and found no difference in terms of upper airway morbidity.

Zhang Guo-hua and colleagues [4] also demonstrated that orotracheal intubation using ILMA and direct laryngoscopy under general anaesthesia produced similar pressor responses, with no significant differences in blood pressure or heart rate at various time intervals. The findings of the present study are consistent with these observations.

Several factors may explain why ILMA-guided intubation does not significantly reduce the hemodynamic stress response compared to direct laryngoscopy. ILMA-guided intubation involves multiple procedural steps, which may prolong apnoea and increase airway manipulation. Additionally, the ILMA exerts pressure on the oropharyngeal structures and cervical vertebrae, potentially stimulating nociceptive receptors and producing sympathetic responses [10]. During ILMA placement, various maneuvers such as repositioning the device, adjusting head and neck position, and manipulating the jaw may also stimulate airway structures and contribute to hemodynamic changes.

Furthermore, ILMA-guided intubation is essentially a blind procedure, and difficulties such as obstruction of the endotracheal tube by the epiglottis or vocal cords may require repeated adjustments of the device, further stimulating airway receptors. Removal of the ILMA after successful intubation can also produce significant stimulation due to friction against airway structures. Additional maneuvers such as advancing the endotracheal tube using a stabilizing rod may also stimulate the tracheal wall or carina, thereby contributing to hemodynamic responses.

However, some studies have suggested that ILMA may produce less hemodynamic stress compared with direct laryngoscopy. For example, Joo and Rose [11] reported that mean arterial pressure was higher in patients undergoing laryngoscope intubation compared with those receiving ILMA-guided intubation. However, in their study, intubation was performed five minutes after insertion of the ILMA, which differs from routine clinical practice.

The incidence of postoperative pharyngolaryngeal complications in the present study was low in both groups. The findings are comparable with those reported by Kihara et al. [6] and Joo and Rose [11], who also reported no significant difference in airway morbidity between ILMA and direct laryngoscopy.

In our study, mucosal trauma was slightly more frequent in the ILMA group compared to the direct laryngoscopy group, similar to the findings reported in Kavitha's study [10]. This may be attributed to increased mucosal pressure exerted by the ILMA cuff against the pharyngeal mucosa. Additionally, bleeding may be more easily detected in ILMA cases due to accumulation of secretions above the cuff. The incidence of sore throat and hoarseness was comparable between the groups.

Conclusion

We conclude that DLS is comparatively a faster method to secure tracheal intubation than blind intubation through the ILMA and offers no advantages over the Macintosh laryngoscope in regard to hemodynamic responses for patients requiring intubation for elective surgery with normal airways, but it is a feasible alternative as Intubating Laryngeal Mask can maintain airway and oxygenation of the patient throughout the intubation procedure, despite taking more time than DLS.

Recommendation: Based on the findings of the present study, direct laryngoscopy using the Macintosh laryngoscope should remain the preferred technique for tracheal intubation in patients with normal airways undergoing elective surgery, as it provides faster intubation with a higher first-attempt success rate. However, the Intubating Laryngeal Mask Airway (ILMA) may be considered a useful alternative airway device as it allows maintenance of ventilation and oxygenation during the intubation process. Adequate training and experience with ILMA may further improve its success rate and reduce intubation time. Future studies with larger sample sizes are recommended to further evaluate the role of ILMA in airway management.

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