Section: Anaesthesiology

Original Research Article

RANDOMIZED CONTROLLED STUDY TO COMPARE THE HEMODYNAMIC EFFECTS FOLLOWING ENDOTRACHEAL INTUBATION USING INTUBATING LARYNGEAL MASK AIRWAY VS. CONVENTIONAL DIRECT LARYNGOSCOPY

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ABSTRACT

Background: Direct laryngoscopy (DL) and tracheal intubation with an intubating laryngeal mask airway (ILMA) can cause significant haemodynamic alterations. To examine the haemodynamic reactions and complications brought on by DL and ILMA, we conducted prospective randomized research. **Materials and Methods:** Sixty patients aged 18 to 55 years, with ASA physical status I or II and Mallampati Class I or II, were randomly divided into two groups. Group A underwent intubation via ILMA, while Group B used a Macintosh laryngoscope. Hemodynamic parameters (heart rate, MAP, SpO2) were recorded before, during, and after intubation. Intubation time, number of attempts, complications, and pharyngolaryngeal morbidities after extubation were also compared. A p-value <0.05 was considered statistically significant. **Results:** The groups were statistically similar in gender, age, and ASA classification. Mean HR, MAP were statistically higher in group B ($p<0.05$); while SpO2 in group A was higher-however within normal limits. Mean intubation time was significantly longer in group A (24.93 ± 3.52 seconds) compared to group B (17.10 ± 2.41 seconds). Group B had more cases of hoarseness (17 vs. 12) and sore throat (4 vs. 1), while esophageal intubation occurred more often in group A (7 vs. 4). Overall, complication rates were comparable between the groups. **Conclusion:** Compared to DL intubation, ILMA laryngoscopy showed reduced hemodynamic variability, fewer complications, and lower pharyngolaryngeal morbidity, suggesting it minimizes the hemodynamic response to tracheal intubation.

INTRODUCTION

Endotracheal intubation has emerged as the norm for managing the airway in unconscious patients. This technique not only facilitates controlled ventilation for extended periods in any position but also enables the clearance of tracheal secretions.[1] Several medical professionals require being proficient in endotracheal intubation in order to secure a patient's airway and enhance breathing and oxygen at various situations.[2]

In an emergency situation, securing the patient's airway and achieving first-pass success are the objectives of endotracheal intubation.[3] The most popular technique to carry out endotracheal intubation is direct laryngoscopy, however there are other approaches as well.[4] After Alfred Kirstein initially developed direct laryngoscopy in 1895, Chevalier Jackson reported a high success rate for endotracheal intubation in 1913 by employing direct laryngoscopy with a light source at the distal tip rather than the proximal, as Kirstein had done.[5,6]

Scientific progress emphasizes developing less traumatic methods for procedures, leading to the evolution of newer techniques and equipment aimed at reducing complications associated with direct laryngoscope usage. In 1985, British anaesthesiologist Dr. Archie Brain developed the Laryngeal Mask Airway (LMA), a supraglottic airway device that allowed breathing control under anaesthesia.[7] These are reusable or single-use extraglottic airway devices that can be used as an emergency life-saving measure in cases of problematic or failing airways, or as a temporary solution to keep the airway open while anaesthesia is being administered.[8,9] LMAs can be used as a rescue tool as well as the primary airway . In the

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case of "cannot-intubate, cannot-ventilate," algorithms recommend the use of an LMA.[8,10]

Cardiovascular responses to endotracheal intubation and direct laryngoscopy is mediated by the vagus (X) and glossopharyngeal (IX) nerves, which activate the vasomotor centre and send afferent signals from the epiglottis and infra-galactic region. This triggers a peripheral sympathetic response which might be lethal in those with heart issues.[11,12]

The advanced version of the LMA originally presented by Dr. Brain et al. in 1997, the intubating LMA (ILMA) is intended to enable blind tracheal intubation with an endotracheal tube in a patient under anaesthesia in addition to allowing ventilation. During apnoea episodes, the ILMA allows oxygenation and ventilatory management in between intubation attempts. An ILMA may be less stimulating than a conventional laryngoscopy (CL) for tracheal intubation since it does not need direct exposure of the larynx.[13,14]

It has been demonstrated by Hickey S et al and Braude N et al that the cardiovascular impact of placing an ILMA is comparable to that of creating an oropharyngeal airway and is less than that of tracheal intubation.[15,16]

Building on this context, we sought to investigate whether there were any clinically significant differences in the hemodynamic response between ILMA-guided intubation and direct laryngoscopic intubation. Thus, this study was conducted to compare mean arterial pressure and heart rate at various time intervals during intubation using these two techniques. Additionally, we aimed to assess the time required for intubation with each device, the number of intubation attempts, and post-extubation pharyngolaryngeal morbidities such as hoarseness and sore throat. Complications, including esophageal intubation, trauma, and laryngospasm, were also documented.

MATERIALS AND METHODS

This randomized controlled study was conducted over one year, from August 2020 to August 2021, in the tertiary care hospital of central India. The study began after obtaining ethical approval EC/MGM/Feb-20/21 and written informed consent from all participants. A total of 60 patients were enrolled and randomly assigned into two groups using a simple random sampling technique, with 30 patients in each group. Group A underwent intubation using ILMA, while Group B underwent direct laryngoscopy (DL).

Eligibility Criteria

Participants aged 18 to 55 years with ASA physical status I and II and Mallampati Class I and II were included. Patients were excluded if they refused participation, had unanticipated difficult intubation, suffered from GERD or had a full stomach, or experienced more than three failed intubation attempts.

Study methodology

After allocation to the two groups, a thorough pre-anaesthetic evaluation was conducted for each patient prior to their scheduled surgery, whether elective or emergency. Patients shifted to the operating room and a multiparameter monitor was connected. Baseline vital parameters were noted, intravenous access secured using an 18G or 20G cannula, and appropriate IV fluids were initiated. Patients in both Group A and Group B were premedicated with Inj. Glycopyrrolate (8–10 mcg/kg) and Inj. Midazolam (0.05 mg/kg). Following this, Inj. Fentanyl (1–2 mcg/kg) was administered three minutes prior to Inj. Propofol (1–2 mg/kg). To facilitate endotracheal intubation, Inj. Succinylcholine (1–2 mg/kg) was administered.

In Group A, the ILMA was first inserted size 4 ILMA for male patients and size 3 ILMA for female patients. Correct placement of the ILMA was confirmed using capnography and bilateral auscultation after connecting it to the anaesthesia circuit. Once proper placement was verified, a well-lubricated 7.5 mm (ID) cuffed endotracheal tube (ETT) was inserted for male patients, and a 7.0 mm (ID) cuffed ETT for female patients. The ETT was then connected to the anaesthesia circuit, and bilateral air entry was confirmed through auscultation.

In Group B, intubation was performed using direct laryngoscopy with a Macintosh blade (size No. 3 or 4), selected based on the patient's height and weight. 7.5 mm (ID) cuffed endotracheal tube (ETT) was inserted for male patients, and a 7.0 mm (ID) cuffed ETT for female patients.

Following intubation, patients in both groups were maintained on a combination of oxygen, nitrous oxide, and isoflurane, with a loading dose of Inj. Atracurium (0.5 mg/kg) and maintenance doses of 0.1 mg/kg. Adequate analgesia was ensured throughout. At the conclusion of surgery, patients were reversed with Inj. Neostigmine (0.05 mg/kg) and Inj. Glycopyrrolate (0.01 mg/kg), and extubation was performed.

Assessment of endpoints

The time taken for intubation was recorded, and vital signs (heart rate, mean arterial pressure, and SpO2) were monitored before (at the time of laryngoscopy when the vocal cords were visualized), during, and after intubation. The number of attempts required for successful intubation was documented for both groups. Any complications encountered during intubation, such as esophageal intubation, trauma (including visible blood detection), or laryngospasm, were noted.

Post-extubation, all patients were observed and monitored for 24 hours for pharyngolaryngeal morbidities, such as hoarseness or sore throat. Patients experiencing these morbidities were managed with appropriate interventions, including steam inhalation, nebulization, and Inj. Dexamethasone (4 mg).

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Statistical Analysis

The data was initially entered into the Microsoft Excel sheet from the customized proforma for analysis. Mini Tab Version 17.0 was used for calculating the p values. Comparison of means between the two groups was done using unpaired 't' test. Descriptive statistics were presented in the form of numbers and percentages and compared using Pearson Chi square test. A p value of <0.05 was taken as statistically significant.

RESULTS

30 patients were enrolled in each group. Regarding demographics, airway characteristics, there were no notable variations between the groups with p>0.05. [Table 1]

Table 1: Demographic characteristics, airway assessments of the groups

Clinico-demographic parameter	Variable under assessment	Group A (n=30)	Group B (n=30)
Age distribution	18-20 years	8 (26.7%)	6 (20%)
	21-40 years	13 (43.3%)	16 (53.3%)
	41-55 years	9 (30%)	8 (26.7%)
Average age in years	Mean ± SD	32.77 ± 13.11	33.27 ± 11.86
Gender distribution	Male	12 (40%)	16 (53.3%)
	Female	18 (60%)	14 (46.7%)
Distribution of ASA class	ASA I	22 (73.3%)	20 (66.7%)
	ASA II	8 (26.7%)	10 (33.3%)

The haemodynamic parameters including HR, MAP and spO2 was assessed at three time-points: before, during and after intubation. The results have been enlisted in. [Table 2]

Table 2: Haemodynamic variable between two groups

Haemodynamic Variable under observation	Time-point	Group A (n=30)	Group B (n=30)	P-value
Heart rate (in beats/min)	**Before intubation**	86.2 ± 11.47	92.77 ± 9.32	0.018*
	During intubation	98.37 ± 10	104.93 ± 9.72	0.012*
	After intubation	96.07 ± 8.04	99.7 ± 9.37	0.1
Mean arterial pressure (in mmHg)	**Before intubation**	92.67 ± 9.5	94.1 ± 9.9	0.56
	During intubation	92.87 ± 9.55	104.03 ± 6.73	0.001*
	After intubation	91.63 ± 8.95	100.73 ± 8.05	0.001*
SpO2 level (in %)	**Before intubation**	99.1 ± 0.31	99.03 ± 0.18	0.28
	During intubation	99.4 ± 0.5	99.03 ± 0.18	0.0003*
	After intubation	99.5 ± 0.51	99.03 ± 0.18	0.0001*

[All values are expressed as the mean±SD. *Represents p<0.05 on unpaired T-test.] difference (P=0.171), indicating comparable results between the groups.

Before intubation, the mean heart rate was significantly higher in Group B (92.77 ± 9.32/min) compared to Group A (86.2 ± 11.47/min) (P=0.018). During intubation, Group B again showed a significantly higher mean heart rate (104.93 ± 9.72/min) than Group A (98.37 ± 10.0/min) (P=0.012). After intubation, the mean heart rate was 99.7 ± 9.37/min in Group B and 96.07 ± 8.01/min in Group A, with no statistically significant difference (P=0.112). Overall, Group B demonstrated a significantly higher heart rate before and during intubation, while the rates were comparable between the groups after intubation.

Before intubation, the mean MAP was comparable between Group A (92.87 ± 9.55 mm Hg) and Group B (94.1 ± 9.9 mm Hg) (P=0.569). During intubation, Group B had a significantly higher mean MAP (104.03 ± 6.73 mm Hg) compared to Group A (92.87 ± 9.55 mm Hg) (P=0.001). After intubation, the mean MAP remained significantly higher in Group B (100.73 ± 8.05 mm Hg) than in Group A (91.63 ± 8.95 mm Hg) (P=0.001). Overall, the mean MAP was similar before intubation but significantly higher in Group B during and after intubation.

Before intubation, the mean SpO2 was 99.1 ± 0.31% in Group A and 99.03 ± 0.18% in Group B. During intubation, it was 99.4 ± 0.5% in Group A and 99.03 ± 0.18% in Group B. After intubation, Group A had a mean SpO2 of 99.5 ± 0.51%, while Group B remained at 99.03 ± 0.18%. Although statistically different, the mean SpO2 in both

Mean intubation time between the two groups were compared (Figure 1). Group B's mean intubation time was 17.10 ± 2.41 seconds, whereas Group A's was 24.93 ± 3.52 seconds. The difference was statistically significant (P=0.001), indicating that Group A required a substantially longer time to be intubated.

In Group A, 23 patients (76.7%) were intubated on the first attempt, while 7 (23.3%) required two attempts. In Group B, 27 patients (90%) were intubated on the first attempt, and 3 (10%) needed two attempts. The mean number of attempts was 1.23 ± 0.43 in Group A and 1.10 ± 0.31 in Group B, with no statistically significant difference (P=0.171), indicating comparable results between the groups.

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In Group A, 12 patients (40%) experienced hoarseness, and 1 (3.3%) had a sore throat, while in Group B, 17 patients (56.7%) had hoarseness, and 4 (13.3%) reported a sore throat. Both sore throat and hoarseness were more common in Group B but statistically insignificant on Chi-square test. Esophageal intubation occurred in 7 patients (23.3%) in Group A and 4 (13.3%) in Group B, with no significant difference on Chi-square test. Trauma or blood during intubation was observed in 3 patients (10%) in both groups. Laryngospasm was not reported in either group. [Table 3]

Table 3: Comparison of outcomes of the intubation techniques

Outcomes of the techniques employed	Observation	Group A (n=30)	Group B (n=30)	p-value
Morbidity	Hoarseness	12 (40%)	17 (56.7%)	0.19
	Sore throat	1 (3.3%)	4 (13.3%)	0.16
Complications	Esophageal intubation	7 (23.3%)	4 (13.3%)	0.3
	Trauma/ blood detected	3 (10%)	3 (10%)	1

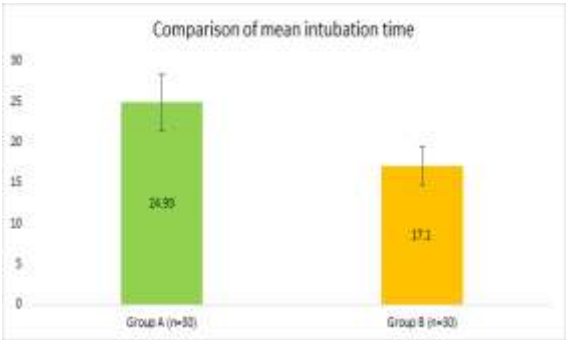

Figure 1: Comparison of mean intubation time

DISCUSSION

Intubation has historically been undertaken via direct laryngoscopy using a Macintosh laryngoscope. Endotracheal intubation and laryngoscopy are two distinct stimuli that cause a pressor reaction. During intubation, it has been necessary to eliminate such reactions. LMA made it possible to provide ventilation and oxygenation in difficult airway scenarios. Nevertheless, this device had a drawback of its own. By serving as both an LMA and an intubation conduit, ILMA was developed to solve the issues associated with LMA.

In the current study, the mean heart rate (HR) was significantly higher in Group B before and during intubation, while it was comparable between the groups after intubation (P>0.05). These findings align with the study by Bharti N et al,[17] which reported a significant HR increase during intubation using a direct laryngoscope compared to ILMA. Similarly, Jarineshin H et al,[18] observed that in three groups—Group 1 (ETT), Group 2 (LMA-C), and Group 3 (LMA-S)—the mean HR at specific time points showed a significant increase in the ETT group compared to the LMA groups at the first (100 ± 18.27), third (91.04 ± 17.12), and fifth minute (85.82 ± 16.01) after intubation. Maharjan S,[19] also found an increase in HR after airway device use in all three groups, with the maximum rise observed after tracheal tube insertion. While baseline HR and HR before airway placement were comparable, significant differences were noted one minute after device use (98.45 ± 13.57) and after device removal (98.03 ± 16.8) (P<0.001 and P=0.021, respectively).

The mean MAP in the present research was substantially higher in Group B during and after intubation than in Group A (P<0.05), although it was equivalent between the two groups before to intubation (P>0.05). The MAP results were similar to those of the study by Bharti N et al,[17] which found that the laryngoscopy group's MAP increased considerably (P<0.05) following tracheal intubation. Nonetheless, the ILMA group's blood pressure increase was negligible and on par with baseline levels. These results also supported a study by Siddiqui NT et al,[20] that found that the DL group experienced a 26% and 13% increase in SBP after intubation compared to the baseline for the first two minutes, while the ILMA group experienced an 8–12% increase. The difference between the two groups was statistically significant (P<0.05). Comparing the DL and ILMA groups to the baseline, the increase in DBP following intubation was 23% and 7%, respectively. The first two minutes after intubation showed a statistically significant difference (P<0.05) between the two groups. Both groups saw statistically significant increase in MAP upon intubation (P<0.05).

The increase in HR in patients who underwent direct laryngoscopy could be attributed to the fact that elevating the epiglottis and exposing the glottis are necessary for orotracheal intubation.ILMA-guided orotracheal intubation does not directly stimulate the laryngeal receptors or stretch the base of the tongue, it offers some benefits. Orotracheal intubation under ILMA guidance may, in theory, result in less harmful cardiovascular stress reactions.[21,22]

Current study showed that the mean SpO2 in both groups was within the normal clinical range, despite the fact that there was a statistically significant difference between them. This supported the findings of the study by Bharti N et al,[17] which showed generally excellent oxygen saturation values.

Group A took significantly more time to intubate than Group B, according to the mean intubation times for the two groups. This was also demonstrated and corroborated in the study by Bharti N et al,[17] which found that the ILMA Group required much more time for a successful intubation than the DL Group. Our findings were similarly

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consistent with research by Sharma VS et al,[23] that found that the group using ILMA needed a considerably longer time to successfully intubate patients than the group using Laryngoscope.

The mean number of attempts in this study was 1.23 ± 0.43 in Group A and 1.10 ± 0.31 in Group B. Even though the difference was statistically insignificant (P=0.171), the mean number of attempts in both groups was comparable. Group A's first attempt intubation success rate was 76.6%, whereas Group B's was 90%. Ten percent of patients in Group B and twenty-three percent of patients in Group A were successfully intubated in two tries. Every patient had a successful intubation. This was comparable to research by Bharti N et al,[17] in which 95% of patients in the laryngoscopy group were successfully intubated on the first try, with the remaining 5% requiring a second effort. Even though the ILMA group's total tracheal intubation success rate was 97.5%, only 87.5% of patients were intubated on the initial attempt

In the current study, hoarseness and sore throat were more common in Group B, similar to Kavitha J et al [24], where the DL group experienced more number of sore throat and hoarseness at 2 and 24 hours post-intubation, as well as difficulty swallowing at 24 hours, though the differences were not significant. However, Bharti N et al,[17] reported higher rates of sore throat (9/40) and hoarseness (3/40) in the ILMA group compared to the DL group (7/40 and 2/40, respectively), with no significant difference.

In our study, esophageal intubation occurred in 7 (23.3%) patients in Group A and 4 (13.3%) in Group B, with trauma/blood during intubation seen in 3 (10%) patients in each group. Esophageal intubation was more frequent in Group A. No laryngospasm was observed in either group. These findings align with Bharti N et al [17], where esophageal intubation occurred in 4/40 ILMA patients, and mucosal trauma was seen in 6/40 ILMA patients compared to 3/40 in the DL group, attributed to higher pharyngeal pressure from the ILMA. Similarly, Sharma VS et al,[23] reported esophageal intubation in 2/30 Group I patients, with mucosal injury in 3/30 Group L and 2/30 Group I patients, with no laryngospasm noted. Differences in these studies were insignificant.

The study is limited by its single centred nature and small sample size. To overcome these limitations, multicentric studies with larger sample size are needed to be conducted to obtain more conclusive results.

CONCLUSION

The hemodynamic response to intubation was lower with ILMA than with laryngoscope-guided intubation. However, compared to direct laryngoscopy, intubation by ILMA was more time-consuming, involved more attempts, and had a greater frequency of esophageal intubation. This is probably because ILMA is less experienced. Laryngoscope-guided intubation was corelated with a higher occurance of pharyngolaryngeal morbidities, including sore throat and hoarseness. Despite these drawbacks, ILMA may eventually replace other methods for regular and challenging intubations because of its capacity to reduce sympathetic stress reactions, which is particularly advantageous for high-risk patients.

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