

Comparison of Endotracheal Intubation through ILMA and Baska Mask: A Randomised Clinical Study

NEETIKA CHAHAR¹, AJAY WAHI², NIYATI SINHA³, RITU GUPTA⁴, SAPNA BANSAL⁵, PRAVEENA REDDY⁶



ABSTRACT

Introduction: Supraglottic Airway Devices (SADs) have established a role in both routine as well as emergency airway management of difficult airways in both children and adults. But anaesthesiologist may need to secure the airway by inserting an Endotracheal Tube (ETT) at any time.

Aim: To evaluate success rate of Baska mask and Intubating Laryngeal Mask Airway (ILMA) for ETT insertion through them by conducting a prospective and randomised study.

Materials and Methods: The randomised clinical study was conducted in 60 American Society of Anaesthesiologists (ASA) status I-II patients scheduled for elective surgical procedures requiring endotracheal intubation through either Baska mask or ILMA. In both the groups, standard induction and insertion technique of SAD was used. Reinforced ETT was used in the first attempt and Polyvinyl Chloride (PVC) ETT in the second attempt for intubation through both SADs. The total time for

intubation, number of attempts taken to insert the SAD and ETT through it, haemodynamic response and adverse events were studied. Data was analysed using Statistical Package for the Social Science (SPSS) version 21.0.

Results: Patients in both the groups were comparable demographically with respect to sex, as a status, age and weight. Successful intubation was achieved in 33.3% (n=10/30) on first attempt through Baska mask compared to 86.7% in ILMA (n=26/30) (p=0.001). The overall intubation success rate was also lower with Baska group (56.7%; n=20/30) compared to ILMA (100%; n=30/30) (p<0.001). The haemodynamic parameters during intubation were also significantly higher in the Baska group as compared to the ILMA group. There were no differences in the other secondary outcomes.

Conclusion: The first pass and overall success rate of intubation through the Baska mask were inferior to those of ILMA.

Keywords: Intubating laryngeal mask airway, Laryngoscopy, Polyvinyl chloride endotracheal tube, Supraglottic airways

INTRODUCTION

Airway management is the most important role of the anaesthesiologist in elective cases under general anaesthesia and in emergency services. SADs are used with discretion for airway management in general anaesthesia. In difficult airway algorithms, they have maintained a status as a rescue option till the gold standard which is an ETT is inserted [1]. Continuous research has led to the development of three generations of SADs with path-breaking advancements that have had a high impact on their safety, ease of use, indications and efficacy [2-4]. There are some situations where a SAD will have more advantages over ETT such as reactive airway, cardiovascular instability and in emergency airway management. Anaesthesiologists or emergency physicians may employ a SAD at the beginning in such scenarios but due to unforeseen circumstances such as prolonged surgery, there may arise a need to secure the airway by inserting an ETT. Then either SAD will be removed and ETT inserted after laryngoscopy or ETT can be inserted through SAD. Exchange of SAD with ETT or with another SAD requires disruption of ventilation and risk of aspiration. Moreover, it may not be possible to conduct laryngoscopy for instance in the prone position. Several studies have explored different generations of SADs to determine the pros and cons of inserting ETT through them. Designed to provide greater success for intubation, ILMA was introduced in clinical practices in 1997 [5]. The study by Shyam R et al., determined that ILMA has a success rate of 100% for intubation [6]. But one may have used a different advanced generation SAD like Baska mask during anaesthesia or emergency airway management.

Baska mask is a third-generation uncuffed SAD that has been designed to enhance the safety from aspiration [2], decrease adverse effects of cuff pressure [7] and ability to ventilate adequately even in case of increased airway pressure [7,8]. The Baska mask

is inserted in the neutral head position and requires minimal neck manipulation [9] that may be advantageous in patients with cervical spine instability.

Therefore, a randomised clinical study was conducted by comparing Baska mask with ILMA for ETT insertion through them. The primary outcome measures studied were to evaluate the first pass success rate of intubation through the device, ease of insertion with number of attempts and overall success of intubation. The secondary outcome measures studied were to record the airway response and haemodynamic changes while intubating through the SAD during this study.

MATERIALS AND METHODS

This randomised clinical study was conducted in Maharishi Markandeshwar Institute of Medical Sciences and Research (MMIMSR), Mullana, Ambala, Punjab, India, in November 2016 to December 2019. Institutional Ethical Committee (approval no. IEC-847 dated 19.11.2016) and informed consent were duly taken.

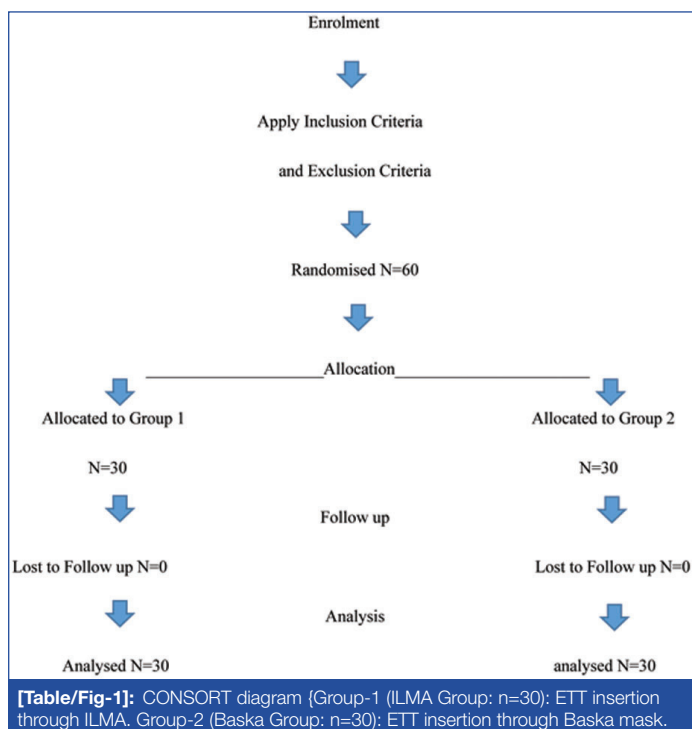
Sample size estimation: was performed using the software MedCalc (year 15.2). The first attempt success rate in the pilot study for the Baska mask was 56.7% and ILMA was 87%. Presuming alpha error as 0.05, beta error as 0.20, and the ratio of cases to control as 1, the calculated sample size was a minimum of 29 in each group.

Inclusion criteria: Patients of age 18 to 60 years, with ASA physical status I-II and scheduled for the elective surgical procedures requiring endotracheal intubation were included in the study.

Exclusion criteria: Patients with difficult airway, reactive airway disease, having increased risk of nausea, vomiting or increased risk of aspiration were excluded from the study.

Study Procedure

The study was conducted by two clinicians, one planner and a thesis candidate. Patients were randomly divided into two groups of 30 patients each using computer-generated random numbers and were blinded to the group they were assigned. The procedure of study participants selection is depicted in [Table/Fig-1].



Anaesthetic technique: Standard Nil Per Os (NPO) guidelines were followed and patients were kept fasting overnight. Tablet alprazolam 0.25 mg was administered to allay anxiety and Tablet ranitidine 150 mg was given a night before and on the morning of surgery for aspiration prophylaxis. The baseline Heart Rate (HR), Non-invasive Blood Pressure (NIBP) and Oxygen Saturation (SpO₂) of the patient were recorded. After securing Intravenous access, the patient received pre-oxygenation for three minutes.

Anaesthesia induction was achieved by giving fentanyl (2 mcg/kg) and propofol (2 mg/kg) followed by succinylcholine (1.5 mg/kg), after adjust spaces. Maintenance of anaesthesia was done with propofol infusion (150 mcg/kg/minute) and with 40% oxygen with nitrous oxide. The SADs were inserted after the completion of neuromuscular blockade. Following sizes of the Baska mask, ILMA and tracheal tubes were used in this study based on the weight of the patients: for less than 50 kg-size 3 and more than 50 kg-size 4. Both ILMA and Baska mask insertion was done according to the standard technique. In ILMA intubation, the gentle and slight rotation of the handle in and out along with side-to-side movement was done until the ventilation of the patient was optimised, after which the handle was lifted anteriorly gently and a tracheal tube was inserted. For the Baska mask, the device was withdrawn 5-8 cm with mandibular lifting in the process of reinserting the Baska mask and after that tracheal tube was reinserted. The cuffed reinforced tracheal tube of appropriate size was inserted through the SADs after lubricating with water-soluble lubricant.

Intubation was labelled successful after checking the ventilation and monitoring end tidal CO₂. If any significant resistance was felt with the reinforced tube or it got slipped into the oesophagus in the first attempt, the next intubation was done with a PVC tube. A reinforced tube was used in all patients using ILMA. After successful intubation was confirmed, SAD was withdrawn carefully by supporting with another ETT to avoid extubation. In case the blind intubation was not done properly in three consecutive attempts or the SpO₂ decreased to 90% then, SAD was withdrawn and direct

laryngoscopy was used for intubation. In this study, standard intraoperative monitoring was carried out. After completion of the surgery, propofol infusion was stopped 15 minutes before the end of surgery. Neuromuscular blockade was reversed with neostigmine (0.5 mg/kg) and glycopyrrolate (0.01 mg/kg). After adequate reversal and assessment of patient responsiveness, extubation was undertaken.

The primary objectives were:

- To measure the total time taken from the moment the SAD was placed until after it was removed with correct placement of ETT verified by capnography;
- The number of attempts taken to insert the SAD and ETT through it and the overall success rate of intubation through SAD.

The secondary objectives were:

- To evaluate preintubation and post-intubation HR and Mean Arterial Pressure (MAP) values immediately and after intervals of one minute to 10 minutes;
- To evaluate the perioperative adverse events: a) Airway response to LMA insertion/intubation (Laryngospasm, bronchospasm, coughing, gagging); b) Desaturation (SpO₂ 90% or less); c) Grossly visible blood on the airway device; d) Evidence of regurgitation of gastric contents;
- To evaluate the postoperative adverse events: sore throat, pain in ears, neck or jaw and hoarseness of voice; (0 hour) and after 24 hours. Soreness was assessed using the Visual Analogue Scale (VAS) 0-10; VAS >3 was considered significant. To evaluate the critical events: failure of insertion/failure to intubate through the device (failure after three attempts)/device failure/aspiration/macroscopic blood on the device.

STATISTICAL ANALYSIS

Quantitative variables for independent samples were compared using Student's t-test and Mann-Whitney U test for parametric and non-parametric data. Categorical data was compared using Chi-square (χ^2) test was performed. Statistical Package for the Social Science (SPSS) version 21.0 was used.

RESULTS

Both groups were comparable in terms of demographic profile [Table/Fig-2]. LMA insertion was 100% successful in both groups. The first attempt success rate of ILMA insertion was 90% in group I whereas 63.3% in group II (p-value 0.019). ETT insertion was successful in 100% of patients in group I whereas only 66.7% in group II (p-value 0.001) [Table/Fig-3]. The intubation success rate in the first attempt was statistically higher with 86.7% in the ILMA group than 33.3% in the Baska mask group [Table/Fig-3]. A 33.3% of patients could not be intubated using a Baska mask but a conventional laryngoscope. Failure to intubate was considered a critical event.

Demographic and clinical details		Group I n (%)	Group II n (%)	p-value
Sex	Female	17 (56.7)	11 (36.7)	0.195
	Male	13 (43.3)	19 (63.3)	
ASA	I	23 (76.7)	23 (76.7)	0.01
	II	7 (23.3)	7 (23.3)	
Age (Year)	Mean±SD	37.17±12.15	35.57±10.74	0.591
Weight (Kg)	Mean±SD	65.73±6.60	63.00±6.84	0.121

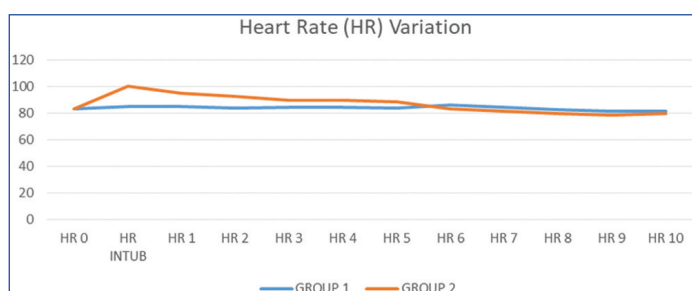
[Table/Fig-2]: Distribution of patients according to ASA and gender, age and weight.

The mean total time from ILMA insertion to intubation in group I was 4.60±0.72 minutes and in group II was 5.97±1.83 minutes [Table/Fig-3]. When compared the difference was statistically significant with p-value <0.05. Mean HR was significantly higher in the group at the time of ETT insertion and till six minutes after intubation

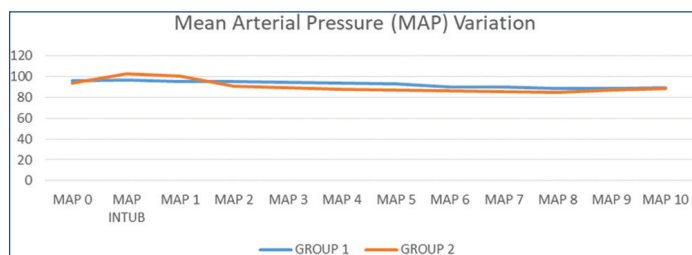
No. of attempts		Group I n (%)	Group II n (%)	p-value
ILMA insertion	1	27 (90)	19 (63.3)	0.019
	2	3 (10.0)	5 (16.7)	
	3	0 (0.0)	6 (20.0)	
Total		30 (100)	30 (100)	<0.001
No. of attempts of intubation	1	26 (86.7)	10 (33.3)	
	2	3 (10.0)	5 (16.7)	
	3	1 (3.3)	5 (16.7)	
Total		30 (100.0)	20 (66.7)	<0.001
Total time from LMA insertion to intubation (minutes)	Mean±SD	4.60±0.72	5.97±1.83	<0.001

[Table/Fig-3]: Distribution of patients according to number of attempts for insertion of supraglottic device.

[Table/Fig-4]. Similarly, MAP was also significantly higher statistically in group 2 than in group 1 from the time of ETT insertion till five minutes after that [Table/Fig-5].



[Table/Fig-4]: Comparison of HR after ETT insertion at various time intervals; Time interval in minutes.



[Table/Fig-5]: Comparing MAP after ETT insertion at various time intervals; Time intervals in minutes.

No patient in both groups had laryngospasm, bronchospasm, gag reflex, obstruction, nausea, vomiting or regurgitation during placement and ear, jaw or neck pain after extubation. Blood on the device was observed in 3 (10%) of patients in group I and 2 (6.7%) of patients in group II with statistically no significant difference (p-value 0.640). Sore throat was experienced by none in group I and 3.3% of patients were observed with VAS score>3 in group II, both groups were comparable with no statistically significant difference (p-value 0.313). There was less hoarseness of voice postoperatively in the ILMA group [Table/Fig-6]. EtCO₂ and SPO₂ after ETT insertion in the two groups remained similar till 10 minutes.

Groups	Group-I n (%)	Group-II n (%)	p-value
Sore throat (VAS >3)	0	1 (3.3%)	0.313
Hoarseness	1 (3.3%)	6 (20%)	0.044
Ear/Jaw/Neck pain	0	0	

[Table/Fig-6]: Comparing post-operative morbidity in both groups.

DISCUSSION

Among the third generation SADs, the latest one is Baska mask, which is cuffless, shaped accordingly to the laryngeal anatomy and presents with an oesophageal seal. The first and foremost advantage of the Baska mask is that one does not require an orogastric tube, as it has two drains and a sump [2]. In 2020 a study by Jayalekshmi

S et al., concluded that Baska mask being a new SAD has many novel features and it creates a higher oropharyngeal seal pressure than the ILMA supreme that leads to improve safety when used in positive pressure ventilation anaesthesia [10]. In 2017, Aziz ARA and Osman YM did a study comparing I-Gel and Baska Mask in obese patients undergoing elective surgeries under general anaesthesia [11]. The authors concluded SADs are suitable for obese patients, but laryngeal seal was better in Baska mask.

Numerous other studies concluded that the Baska mask is one of the most efficient SAD when used for general anaesthesia. Elective or emergency clinical scenarios may emerge where one may have to use it as a conduit for intubation. However, it has never been evaluated for ETT insertion through it. The present randomised study was undertaken to compare ETT insertion through two SADs, ILMA (Fastrach) and Baska mask in anaesthetised paralysed adult patients undergoing elective surgeries with respect to the number of attempts, insertion time, ease of insertion, haemodynamic stress and post-operative complications.

Till date no study is available in literature comparing intubation through ILMA vs Baska mask to the best of our knowledge. In a study done by Sachidananda R et al., I gel and Baska masks had similar performance in terms of success rate and insertion time with the Baska mask having more sealing pressure [12]. So studies done on newer SADs as I gel were considered for discussion. I gel and Baska both have shorter and broader airway channels than other SADs, enabling insertion of the adult-size ETT. Both the groups were comparable demographically and there was statistically no significant difference with regard to mean age, sex, weight and ASA grading.

In the present study, the success rate for ETT placement in the first attempt was higher with ILMA (86.7%) as compared to Baska (33.3%). The number of attempts required and failure rates (33.3%) were also higher in the Baska group. The mean total time from SAD insertion to intubation in the Baska group was also higher as compared to the ILMA group. The studies of Halwagi AE et al., and Naik L et al., also observed a higher success rate of PVC ET tube insertion with ILMA as compared to I gel [13,14]. This could be due to V shape tracheal tube guiding ramp in ILMA. It centralises the ETT towards the glottis aperture as the ETT emerges from the metal shaft and guides it anteriorly. It could also be due to the presence of the handle in ILMA which resulted in stabilisation and manipulations which cannot be done in I gel or Baska mask. The study by Malhotra SK et al., concluded that conventional PVC tube insertion can have increased success rate with Air-Q as compared to ILMA in case intubation with reinforced tube fails [15]. On this basis, sequence of use of ETTs for intubation through both SADs was planned. There was a statistically significant increase in HR and MAP after intubation in the Baska mask group as compared to the ILMA group from the time of ETT insertion to five minutes after ETT insertion. This again indicates that it is difficult to insert the tube via the Baska mask resulting in repeated stimulations of the larynx due to manipulation of the tube and mask.

Different techniques have been used by the researchers to increase the success rate and decrease the time taken in intubation via SADs such as pre-warming the ETT [16], using a light wand [17], fiberoptic guidance [18], clockwise and counter-clockwise manipulation of the PVC ETT [19], using bougie [20] or the Aintree Intubating Catheter [21] as a conduit and using both of them simultaneously. But fiberoptic guidance will be available only in advanced centres and there too only in operation theatre suites. Changes in SpO₂ and EtCO₂ were statistically insignificant at all time intervals (p>0.05). In group I, hoarseness was seen in 3.3% of patients and in group II in 20% of patients (p-value 0.044). There was less hoarseness of voice postoperatively in patients in the ILMA group. This again corroborates with the above explanation for haemodynamic changes. No other post-operative morbidity was statistically

significant. After ETT was inserted through them, both the devices were able to successfully oxygenate and ventilate the patients in the present study. This observation is similar to the study by Metterlein T et al., where other newer SADs were compared for ETT insertion through them [22].

Limitation(s)

Since, it is the first study of its kind, comparing these two devices and it was unblinded, it is recommended to carry out more studies in future to reach a more precise conclusion. Future researchers can add prewarming the tube, fiberoptic bronchoscopy to the study or modification in insertion such as using a ventilating catheter like Aintree or a bougie as a bridging step.

CONCLUSION(S)

In the present study, it has been observed that as compared to Baska, ILMA is more suitable for ETT insertion through the device. However, intubation can still be done through Baska mask if need arises. Further research on this topic may suggest methods to improve on the success rate noted in the present study.

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PARTICULARS OF CONTRIBUTORS:

1. Resident, Department of Anaesthesia, MMIMSR, Ambala, Haryana, India.
2. Associate Professor, Department of Anaesthesia, Gian Sagar Medical College, Banur, Patiala, Punjab, India.
3. Assistant Professor, Department of Anaesthesia, Rama Medical College, Hapur, Uttar Pradesh, India.
4. Associate Professor, Department of Anaesthesia, MMIMSR, Ambala, Haryana, India.
5. Professor, Department of Anaesthesia, MMIMSR, Ambala, Haryana, India.
6. Resident, Department of Anaesthesia, MMIMSR, Ambala, Haryana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Ritu Gupta,
H. No. Phase 4, Mohali-160059, Punjab, India.
E-mail: guptaritz@gmail.com

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