(International Print/Online Journal)

SJIF IMPACT FACTOR: 5.565
PUBMED-National Library of Medicine ID-101739732

ISSN (Print): 2209-2870
ISSN (Online): 2209-2862

International Journal of Medical Science and Current Research (IJMSCR)
Available online at: www.ijmscr.com
Volume 5, Issue 5, Page No: 957-967
September-October 2022

IJMSCR

Laryngeal Mask Airway(Lma) Guided Intubation: A Prospective Randomized Control Trial Comparing Blockbuster Lma And Intubating Lma (I-Lma) For Ease Of Intubation

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Type of Publication: Original Research Paper
Conflicts of Interest: Nil

Abstract

Background: Supraglottic airway device has been adopted as a bridge to connect ventilation and tracheal intubation. Intubating LMA is designed to facilitate blind intubation without the need for Laryngoscopy. Blockbuster LMA is a newly developed second-generation LMA, specially designed for spontaneous ventilation and endotracheal intubation. This study was conducted to evaluate the ease of intubation using either of these LMAs.Methods: Fifty patients of age group 18 to 60 years undergoing general anesthesia were randomized into 2 groups, of which 25 patients each, for tracheal intubation using either intubating LMA (Group A) or the Blockbuster LMA (Group B). After induction of anesthesia, LMAs were inserted and on achieving adequate ventilation with the device. Blind intubation was attempted through the supraglottic airway device**.**

Aim Of The Study: The primary objective was to find the ease of intubation and the secondary objective was to find out the time needed to insert LMA, manipulation needed, failure and complications.

Methods: After obtaining institutional ethical committee approval, written informed consent was taken from all the 50 patients of American Society of Anesthesiologists (ASA) physical status I & II, modified mallampati classification (MPG) I & II, aged between 18 to 60 years undergoing elective surgeries under general anesthesia between December 2018 and December 2019. Exclusion criteria included patient's refusal, mouth opening less than 2 cm, oral cavity lesions, morbid obesity, pregnancy, and bowel surgeries. Patients were randomly allocated into two groups – Group A (Intubating LMA) and Group B (BlockBuster® LMA), with 25 patients in each group. Random allocation into these groups was done by computer-generated random numbers. Group allocations were placed in sealed, opaque envelopes on initial randomization. An anesthesiologist with experience of 30 successful insertions and intubations with both the devices performed blind tracheal intubation using either of the LMAs. The same anesthesiologist performed all the intubations. Observation and data collection was done by an independent observer**.**

Results: Intubating with Blockbuster LMA was easy when compared with Intubating LMA. The time needed to insert LMA is longer in Intubating LMA than Blockbuster LMA(p=0.0097). The time needed to insert the Endotracheal tube through Intubating LMA is longer than Blockbuster LMA (p=0.001). Complications such as sore throat and bloodstain are also less with Blockbuster LMA.**Conclusion:** Blockbuster LMA provides easy blind intubation with fewer complications. There was no incidence of lip trauma, dental trauma, and blood-tinged secretions over the SAD or ETT in any of the patients in both groups. None of the patients in both the groups complained of dysphonia, dysphagia, and hoarseness.

Keywords: BlockBuster, I-LMA, Laryngeal Mask Airway, Intubation

Introduction

Endotracheal intubation is a definitive way of securing the airway and is routinely done by laryngoscopy and visualization of cords. However, this involves distortion of the upper airway to bring glottis into the line of sight1 and in some situations such as high larynx, facial trauma, etc., tracheal intubation fails. Supraglottic airway devices (SADs) are useful in such situations for rescue ventilation.[1] Laryngeal mask airway (LMA) classic (c-LMA) is one such device that is included in Difficult Airway Society guidelines for unanticipated difficult intubation. Laryngeal mask airway classic was designed for maintenance of airway in emergencies, especially by untrained personnel. Later it was modified into intubating LMA (ILMA) or LMA Fastrach. [2]The major difference between standard LMA and LMA Fastrach lies in the design and function of the shaft which is rigid as compared to the soft silicone shaft of c-LMA thus facilitating adjusting maneuvers to align the mask's aperture against the glottis opening. The i-gel is a relatively new single-use SAD which does not have an inflatable cuff. It is made from a soft, gel-like, and transparent thermoplastic elastomer (styrene-ethylene butadiene styrene) which creates a noninflatable seal which is a mirror impression of the supraglottic anatomy. The i-gel has several other useful design features including a gastric channel, an epiglottic ridge, and a ridged flattened stem to aid insertion and reduce the risk of axial rotation. In 2012 a newer LMA called Blockbuster LMA was invented by professor Ming Tian, who is also the co-president of the international airway management society.[3] They claim that the LMA has better hypopharynx ventilation and provides a better green channel for intubation via the LMA. Because of the make of the LMA, it is claimed to produce lesser post-intubation tachypnoea and reduced aspiration risk due to the gastric port. In blockbuster LMA The airway tube is short and more than 95 degrees angulated. It matches the oropharyngeal curve and makes the insertion easier and less traumatic.[4] The guidance device allows the endotracheal tube to be directed towards the laryngeal opening at a 30-degree angle which enhances the success rate of blind intubation. intubating capability with Blockbuster ET Tube with Soft tip(parker Flexi tip) located at the center line and straight wire-reinforced tube body facilitate the intubation and reduce lesion to the mucosa. Optimal seal pressure - the average seal pressures are around 30cm H2O which is more than the minimum pressure needed in an LMA (25 cm H2O) to prevent gastric regurgitation[5].

Methods: This study was performed by the principles of the Declaration of Helsinki. This study was registered with Clinical Trials Registry-India (CTRI/2018/10/015911). After obtaining institutional ethical committee approval, written informed consent was taken from all the 50 patients of American Society of Anesthesiologists (ASA) physical status I & II, modified mallampati classification (MPG) I & II, aged between 18 to 60 years undergoing elective surgeries under general anesthesia between December 2018 and December 2019. Exclusion criteria included patient's refusal, mouth opening less than 2 cm, oral cavity lesions, morbid obesity, pregnancy, and bowel surgeries. Patients were randomly allocated into two groups – Group A (Intubating LMA) and Group B (BlockBuster® LMA), with 25 patients in each group. Random allocation into these groups was done by computer-generated random numbers. Group allocations were placed in sealed, opaque envelopes on initial randomization. An anesthesiologist with experience of 30 successful insertions and intubations with both the devices performed blind tracheal intubation using either of the LMAs. The same anesthesiologist performed all the intubations. Observation and data collection was done by an independent observer. Patients were kept by nil per oral (NPO) for 6 hours for solid foods before surgery.upon arrival in the operation theatre, 2 large-bore iv lines were secured with an 18G intravenous catheter. Standard monitors were attached such as noninvasive blood pressure (NIBP), pulse oximetry (SPO2), electrocardiograph (ECG), and end-tidal carbon dioxide (ETCO2).Premedicated with intravenous glycopyrrolate 0.02mg/kg, midazolam 0.02mg/kg and fentanyl citrate 2mcg/kg. All patients were pre-oxygenated with 100 % oxygen for 3 minutes and anesthesia-induced with intravenous propofol 2 mg/kg in slow incremental dose and adequacy of mask ventilation was noted.After confirming adequate mask ventilation intravenous succinylcholine 1.5mg/kg was administrated for facilitation for LMA insertion and tracheal intubation. After the complete neuromuscular blockade, either of the devices was inserted using a midline insertion technique in a neutral neck position.

The appropriate size of LMA was selected according to body weight. Size 3 for (30-50kg) and size 4 for (50- 70kg) as per the manufacturers guidelines.A standard method is a midline approach with the cuff fully deflated and the mask aperture facing forward. The dominant hand is used to hold the LMA like a pencil at the distal end of the insertion tube, with the index finger wedged in the groove created by the attachment between the insertion tube and the mask. The LMA has inserted midline into the mouth and the distal end of the mask is juxtaposed against the proximal hard palate so that the tip of the mask is angled caudad. The LMA is then advanced while the index finger applies pressure in a mainly cephalad and slightly posterior fashion. The index finger follows the LMA along the palatopharyngeal arch into the hypopharynx. The opposite hand is used to secure the proximal end of the LMA as the index finger is removed and the LMA is advanced until resistance is felt. The cuff is gently inflated allowing the mask to conform to the shape of the hypopharynx.Adequate ventilation was confirmed by chest movements and ETCO2 waveforms. The lungs were ventilated with a mixture of oxygen and nitrous oxide. The time required for insertion of LMA was defined from removal of the facemask to the time where adequate ventilation was established through LMA with normal square wave capnogram. Adequate ventilation was defined by easy bag ventilation, bilateral equal air entry, and absence of audible air leak around the cuff. Soon after the insertion, the LMA cuff was inflated with air. The LMA was connected to the breathing circuit. The number of attempts for LMA insertion was noted. The ease of LMA placement was assessed using a subjective scale of 0-3 (0-failed, 1- with moderate difficulty, 2- with mild difficulty, and 3 - easy).The oropharyngeal seal pressure was measured with the expiratory valve closed and fresh gas flow of 3L/m until equilibrium was seen on the pressure gauge (not allowed to exceed 40cm H2 O)The time for successful tracheal intubation started when the endotracheal tube was inserted into the green channel of LMA until the confirmation through the capnographic waveform. Intubation was performed blindly through the LMAs, using LMA specific tubes like BlockBuster® tubes (Parker flex tip) and Fastrach® tubes (armored silicone tip). The number of intubation attempts was also noted. Time for successful tracheal intubation was measured. For the group, A blind intubation in the first attempt was done with the Chandy maneuver which consists of 2 steps. The first step, which is important for the establishment of optimal ventilation, is performed by slightly rotating the device in the sagittal plane using the metal handle until the least resistance to bag ventilation is achieved. The second step of the Chandy maneuver is performed just before blind intubation and consists of using the metal handle to slightly lift (but not tilt) the Intubating LMA away from the posterior pharyngeal wall. This facilitates the smooth passage of the ETT into the trachea. For a failed first attempt, the second attempt was done using manual recommendations as mentioned below: If resistance was felt after advancing the ETT 3 cm beyond the distal opening of the Intubating LMA tube, the device was too small, and a larger Intubating LMA was used.If resistance was felt within 1 cm when trying to advance the ETT, the device was too large, and a smaller Intubating LMA was used.If resistance was felt 2–2.5 cm beyond the distal opening of the Intubating LMA tube, the epiglottis had become down-folded during insertion and was not within reach of the epiglottic elevating bar (EEB). In this case, the Intubating LMA was partially withdrawn and reinserted. Following successful intubation, the device was removed based on the manufacturers' recommendations using a removable stylet as a stabilizing rod. The intubation was stated as failed when it was not successful even after five attempts and if the tube was dislodged during the removal of LMA. At the end of the procedure, the tube was removed if standard extubation criteria were met. Complications such as sore throat, blood staining on the device, vomiting, bronchospasm/laryngospasm, post-extubation stridor, etc., were noted. The incidence of sore throat was recorded using a yes/no questionnaire. Nausea is defined as a feeling of sickness with an inclination to vomit. Vomiting is defined as the forceful expulsion of contents of the stomach out through the mouth. Assessed by a 5-point scale, 0- no complaints, 1- mild nausea, 2- moderate nausea and vomiting, 3- frequently vomiting, and 4- Severe continuous vomiting. All these complications were assessed at frequent time intervals like immediate postoperative, every 15 minutes for 2 hours then 4th hourly for 8 hours, and then at 6, 12, 24 hours.

Statistical Analysis

The sample size was calculated using Stat Mate version 2.00 for Windows (GraphPad Software, La Jolla California USA, www.graphpad.com). Based on a pilot study, the success rate of intubation with Intubating LMA was found to be 84% based on the scoring system, with the power of study set at 80% and α error less than 0.05, the effect size of 92% success rate, the sample size was found to be 24. To compensate for dropouts, $n = 25$ subjects were enrolled in each group. Data were analyzed regarding normal distribution by D'Agostino and Pearson Test (omnibus normality test). Normally distributed data were analyzed by one- way-ANOVA, followed by Bonferroni correction for multiple comparisons inappropriate. Non-normal data were analyzed by the Kruskal-Wallis test. Proportions were compared with Fisher's exact test or the Chi-square test, as appropriate. Study data are presented as mean (SD) or median (IQR).

Results:

Demographic variables like age, weight, gender, ASA status, and modified mallampati classification status were all comparable between the groups. Successful LMA device placement in both groups was achieved on the first attempt in all 50 patients. Ease of intubation was statistically significant in Group B (Blockbuster LMA) than Group A (Intubating LMA). 72% of patients were intubated easily, 20% with mild difficulty, and 8% with moderate difficulty. There was a significant. difference in the oropharyngeal seal pressure between the groups. It was 31.8 ± 2.1 cm H2O in Group B and 23.4 ± 1.9 cm H2O in Group A, p=0.001. The time for LMA insertion was lesser in Group B (32.6 ± 11.9 seconds) than in Group A (43.5 ± 16.4 seconds), p=0.0097. The time for endotracheal intubation through LMA s was lesser in Group B (17.8± 5.6 seconds) than in Group A (24.9 ± 9.1 seconds), p= 0.001. Complications like the incidence of sore throat in Group B 12% (3/25) is lesser than Group A 52% (12/25), p= 0.001. Incidence of blood staining in Group B 4%(1/25) is lesser than Group A 20% (5/25) p= 0.04.In Group A 56% of patients were intubated easily, 32% with mild difficulty, and 12% with moderate difficulty. In Group B.

Table:1 Demographic Data

Demographic data	**Group A**	**Group B**
Age in years	38 ± 16	**39 ± 14**
Weight in kgs	59 ± 12	**60 ± 13**
Gender M:F	12:13	**11:14**
ASA 1 :2	15:10	**12:13**
MPG 1 :2	14:11	**13:12**
Duration of Surgery in minutes	**118 ± 15**	**121 ± 12**

Table:2 Variables

Variables	**Group A**	**Group B**	**P-**

			value
Time for LMA insertion (s)	43.5 ± 16.4	32.6 ± 11.9	**0.0097**
Time for	24.9 ± 9.1	17.8 ± 5.6	**0.001**
Intubation (s)			
Ease of Intubation 3:2:1	**14:08:03**	**18:05:02**	**0.04**

Figure :1 Lma- Laryngeal Mask Airway

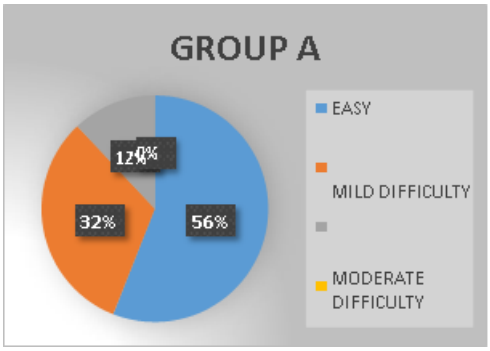


Figure 2: Ease Of Intubation

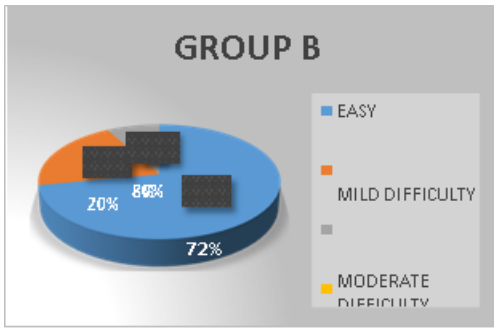
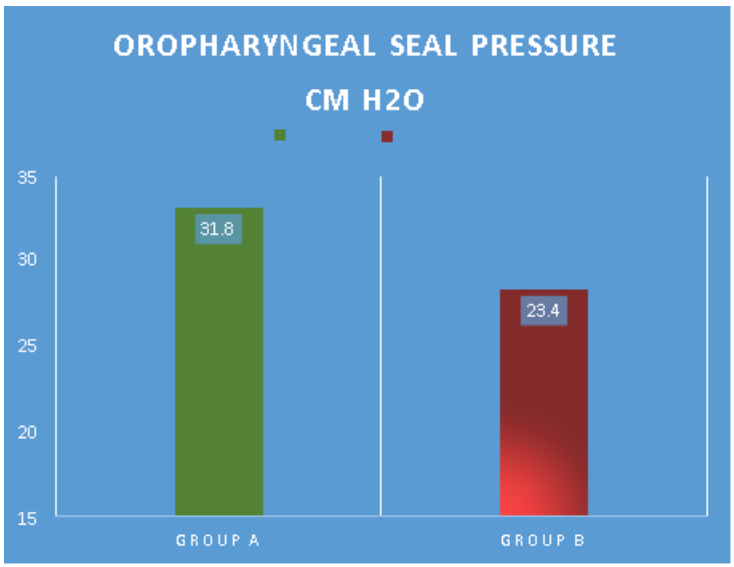


Table 3: Complications

COMPLICATIONS	GROUP A	GROUP B	P-VALUE
Sore throat %	48% (12/25)	12% (3/25)	0.0001
Nausea and vomiting %	8% (2/25)	24% (6/25)	0.12
Blood stain %	20 % (5/25)	4% (1/25)	0.04
Vomiting	0	0	
Aspiration	0	0	
Hemodynamic instability	0	0	

Laryngospasm	0	0	

Figure 3: Oropharyngeal Seal Pressure



Discussion:

In our study ease of intubation with Blockbuster, LMA was intubated easily was 72 % with any difficulty (mild or moderate) which is comparable with the previous study. The success of first attempt success in Intubating LMA was 56% similar to Liu et al. Our results of first-pass success do not correspond with Wang et al. because they compared intubation through BlockBuster LMA concerning sevoflurane concentration which was not so in our study. The reason for such a high success rate of intubation through BlockBuster [7] LMA is because of suitable anatomy and alignment of the LMA, the airway tube is >95° angulated and short which aligns with the oropharyngeal curve. Parker flex, the inverted tip of the BlockBuster tube helps to overcome impingement of the tube to the anterior tracheal wall during intubation that finds a way in the least resistant areas and the angle made by the BlockBuster tube while coming out of the cuff is around 30° while it is 40°in Intubating LMA as stated by ShuaiZ, Jin Z, et al [8]. The overall success rate of insertion of the devices in both groups was 100% which was similar to various previously conducted studies. Both the devices were easy to insert with grades being 1 or 2 similar to previous studies. Time for intubation was significantly less in Group B than Group A. The reason for the lesser time for intubation in Group B is evident based on the shape and anatomy of the LMA and short airway tube. Our results are similar to previous studies.[9,10]

Oropharyngeal seal pressure is often used as a surrogate marker for the quality of the airway seal. The clinical implication of higher seal pressures is that such devices provide better and higher peak inspiratory pressures and aid in positive pressure ventilation. In this study, Group B demonstrated higher seal pressures than Group A. The seal pressures were similar to previous studies. The reason for such high seal pressure is because of an additional dorsal cuff of BlockBuster LMA which improves scalability and may reduce the risk of aspiration.[11]The supraglottic injury score or complication rates like sore throat were less in Group B when compared to Group A because of low resistance exerted by BlockBuster tube during passage causing reduced subglottic mucosal injury. The results were similar to Keller C et al. [12]Although BlockBuster LMA and Intubating LMA have a similar overall success rate of intubation, Block Buster LMA is the preferred choice, because it provides quick and reliable security of airway with good sealing capacity, making it useful for positive pressure ventilation.[13] It has less pharyngeal stimulation causing lesser post-use complications. In addition to all this, it has

extubation capability which helps in safer extubation, with fewer complications. The limitations of our study are that the sample size is small, higher sample size is needed to confirm the outcomes. We did not use fiberoptic bronchoscopy to find out the exact position of both devices. For ease of intubation, we use a subjective scale. [14,15]

Conclusion: Blockbuster LMA provides easy blind intubation with fewer complications. There was no incidence of lip trauma, dental trauma, and blood-tinged secretions over the SAD or ETT in any of the patients in both groups. None of the patients in both groups complained of dysphonia, dysphagia, and hoarseness.

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