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THE BLOCKBUSTER LMA: A Prospective Cohort Study to evaluate the safety and efficacy of the device.

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Abstract:

Background and Aim

The Blockbuster Laryngeal Mask Airway (LMA) is a newer supraglottic airway device which is said to be effective for ventilation and intubation. In our study, we wish to evaluate the combined safety and efficacy of the Blockbuster LMA during blind tracheal intubation.

Materials and methods: We included sixty patients in our study who were American Society of Anesthesiologists (ASA) I-II and aged between 18 - 60 years. Induction was done using intravenous fentanyl 2µg/kg, propofol 2mg/kg and atracurium 0.5 mg/kg (premedication with intravenous glycopyrrolate 0.2mg and midazolam 0.2mg/kg). The Blockbuster LMA was gradually introduced into position and the cuff was inflated with air. The ability to ventilate was confirmed via bilateral chest rise and capnography. Patients were intubated blindly through the Blockbuster laryngeal mask with a specific endotracheal tube provided by the manufacturer. The time required for insertion, ease of insertion, number of attempts, manoeuvres applied, time for intubation, intubation success rates, intraoperative hemodynamic changes, intraoperative airway dynamic changes, and post-operative laryngopharyngeal complications were documented.

Results: All patients were intubated easily in a single attempt except one patient in whom a very large epiglottis was visualized under direct laryngoscopy. Time to successful insertion was 14.2 + 4.8 seconds and time to successful intubation was 11.7 + 5.4 seconds. There were no significant changes in the airway or hemodynamic parameters.

Conclusion: Blind intubation through the Blockbuster LMA has a 98.33% success rate with many advantages. It is a far better choice in difficult airway management.

Keywords: General anesthesia, blind tracheal intubation, direct laryngoscopy.

Introduction

To secure an airway is the vital responsibility of anesthesiologists. Laryngeal mask airway (LMA) is a new concept and boon in airway management, developed by British Anesthesiologist Dr Archie Brain in 1983. [1, 2] A supraglottic airway device (SAD) having a passage for blind

tracheal intubation is gaining popularity as a conduit connecting intubation and ventilation in all genres of patients.

A new LMA known as the Blockbuster LMA by Prof. Ming Tian in 2012 has gained popularity in providing increased safety and efficacy while securing the airway and maintaining a good quality of anesthesia. The Blockbuster LMA has a dual advantage as it provides a channel for ventilation and for intubation. [3] There are some unique features in this LMA, most importantly the 95 degrees angulations which makes ventilation and intubation easier through it. It also provides better sealing pressures at lower volumes. Addition of a gastric tube is also a boon with this LMA. For the purpose of intubation, a silicone wire reinforced tube which has a Parker Flex Touhy-tip is recommended. This is known as the Blockbuster tube. The soft, flexible, blunt edge of the tube causes less mucosal damage during intubation.

There have been many studies where they have compared the success rate of blind intubation using the Blockbuster LMA. [4, 5] We, however, chose to evaluate the safety and efficacy of blind tracheal intubation via Blockbuster LMA. The hypothesis of this study was that the Blockbuster LMA provided higher sealing pressures at lower volumes. The lesser angle of emergence of the tube (30°) along with its unique tip allowed it to enter nonresistant areas easily. Due to these reasons, we get a better success rate during blind tracheal intubation. [5]

Methods

In this study, we enrolled 60 American Society of Anesthesiologists (ASA) I–II patients after getting approval of the institutional ethics committee. All the patients fell in the age group 18–60 years and were scheduled for various routine surgeries under general anesthesia. This was a prospective observational randomized double-blinded study conducted from February 2019 to January 2019. This clinical trial is registered with the Clinical Trial Registry-India (CTRI) (trial registry number: CTRI/2019/12/022336). We used the exclusion criteria of patient refusal, any oral and pharyngeal pathology, a mouth opening of < 2 fingers, pregnancy and morbid obesity. We performed this study in accordance with the principles of the Declaration of Helsinki.

In the study, the patient selection was conducted after randomization done by a computer-generated number table. After taking the written informed consent, an anesthesiologist with an experience of 20 successful insertions and intubations with the Blockbuster LMA performed blind tracheal intubations through this device. All the intubations were also done by the same anesthesiologist. An independent observer did all the data collection.

All the patients remained fasting for 8 hours before surgery and were given tablet alprazolam 0.25mg and tablet ranitidine 150mg the night before surgery as a premedication. On arrival to the operating room, intravenous fluid (ringer lactate /normal saline) was started. A multi-channel monitor showing pulse rate, electrocardiography, oxygen saturation, non-invasive blood pressure and end-tidal carbon dioxide ($EtCO_2$) was connected and a baseline reading was recorded. The patients were pre-medicated with intravenous midazolam 0.02 mg/kg, glycopyrrolate 0.2 mg and fentanyl 2μg/kg. The patients were pre-oxygenated with 100% oxygen for 3 minutes and the induction of anesthesia was done with intravenous propofol 2 mg/kg in slow incremental doses till adequate mask ventilation was achieved. After confirming the adequacy of mask ventilation,

ISSN 2515-8260 Volume 10, Issue 03, 2023

atracurium 0.5 mg/kg i/v was administered for the neuromuscular blockade and the patient was ventilated for 3 minutes with O_2 and sevoflurane 2%. Then the device was inserted in a neutral neck position using a midline insertion technique. An appropriate size of Blockbuster LMA (size 3 or 4) was selected according to body weight. For 30-50kg size 3 and for 50-70kg size 4 was chosen as per the guidelines provided by the manufacturer. [5, 6] After insertion of the LMA, its cuff was inflated with air (max 30mL). If there was a difficulty in the insertion of the Blockbuster LMA, it was removed and reinserted into the mouth. If still there was a difficulty a different size of LMA was chosen. If still, we encountered any problem with ventilation, the patient was excluded from the study. On successful placement of the LMA, we maintained anesthesia using 1-2% sevoflurane, 66% nitrous oxide, 33% oxygen and atracurium. We confirmed the correct placement of the LMA with equal bilateral chest inflation, a square wave capnography and no oropharyngeal leak maintaining peak airway pressures of $\geq$ 20 cm H_2O. The patient was then ventilated with oxygen and sevoflurane for an end-tidal concentration of 2%. [7] The time required for insertion of the LMA was defined from the removal of the facemask to the time where adequate ventilation was established through the LMA with normal square wave capnogram. The adequacy of ventilation was defined by the ease of bag ventilation, bilateral equal air entry and absence of an audible air leak around the cuff. After the insertion, the cuff of Blockbuster LMA was inflated with air using Smiths cuff pressure manometer as per the recommendations, to a pressure of 60 cm H_2O. The LMA was then connected to the breathing circuit and number of attempts for the insertion of the LMA was noted. The ease of LMA placement was assessed using a subjective scale of 1-4 (1-no resistance, 2-mild resistance, 3-moderate resistance, and 4-inability to place the device). [8] We confirmed the successful placement of the device if it achieved a tidal volume of at least 7 ml/kg with a square wave capnogram. The oropharyngeal seal pressure was measured with the expiratory valve closed and fresh gas flow of 3L/min until equilibrium was seen on the pressure gauge (not allowed to exceed 40cm H_2O). [9]

We inserted a lubricated Blockbuster tube through the Blockbuster LMA into the airway of the patient for intubation. The correct placement of the tube was confirmed by bilateral equal air entry and a capnograph tracing. On successful intubation, the laryngeal mask airway was removed and the machine end of the tube was connected to the anesthesia machine. We judged the ease of intubation through the LMA by the time taken from disconnection of the LMA to the point where tracheal tube was placed and the entry was confirmed along with the number of attempts taken to achieve intubation successfully.

The intubation through the Blockbuster LMA was limited to three attempts and force was not used to advance the endotracheal tube so as to avoid airway trauma. If the tracheal tube could be passed without any resistance through the LMA it was considered as the first attempt. When resistance was encountered, then according to the length at which the resistance was encountered, different manoeuvres were used to align the bevel which included Chandy's manoeuvre and twisting of the tracheal tube. This was considered as the second attempt. If still, intubation was not successful a third attempt was made in which we used an up and-down

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movement of the tracheal tube for intubation. When intubation was successful the LMA was removed via standard removal technique using a stabilizing rod provided by the manufacturer. If after three attempts intubation was unsuccessful, the procedure was abandoned and then tracheal intubation was performed under direct laryngoscopy. We recorded the number of attempts taken for intubation and the manoeuvres applied during the process. We also recorded post-operative complications which included complains of sore throat, nausea/vomiting and hoarseness immediately after the surgery, then after one hour, four hours and eight hours post-extubation.

In these patients, sore throat was defined as pain, scratchiness or irritation of throat which worsens on swallowing. It was assessed by a 4 point scale, 1- no sore throat, 2- mild (sore throat only on inquiry), 3- moderate (sore throat without inquiry), and 4- severe (sore throat with soreness and associated throat pain). Nausea was defined as a feeling of sickness with an inclination to vomit. Vomiting was defined as a forceful expulsion of contents of the stomach out through the mouth assessed by a 5 point scale, 1- no complaints, 2- mild nausea, 3- moderate nausea and vomiting, 4- severe continuous vomiting. All these complications were assessed at time intervals like the immediate post-operative period then at one hour, four hours and eight hours post-extubation.

Results

The demographic information and summary of the results are presented in [Table 1] and [Table 2], respectively. We recruited 60 patients for our study so as to increase the power of our study and also to allow for possible dropouts as shown in the consort chart [Figure 1]. No patients were excluded after enrolment. Insertion of the Blockbuster LMA was successful in all the patients in the first attempt. Ventilation was also successful in all patients. However, in two patients we encountered moderate resistance while inserting the LMA. Intubation was successful in all the patients in the first attempt except four patients in whom a second attempt was required. Intubation was unsuccessful in a single patient in whom a very large epiglottis was visualized under direct laryngoscopy. The LMA was removed easily in all 60 patients without trauma. No patient experienced desaturation, laryngospasm or airway obstruction during the study [Table 3]. The hemodynamic response to Blockbuster insertion and intubation is depicted in [Table 4]. The post-operative complications are shown in [Table 5].

ISSN 2515-8260 Volume 10, Issue 03, 2023

Figure 1: Consort Chart

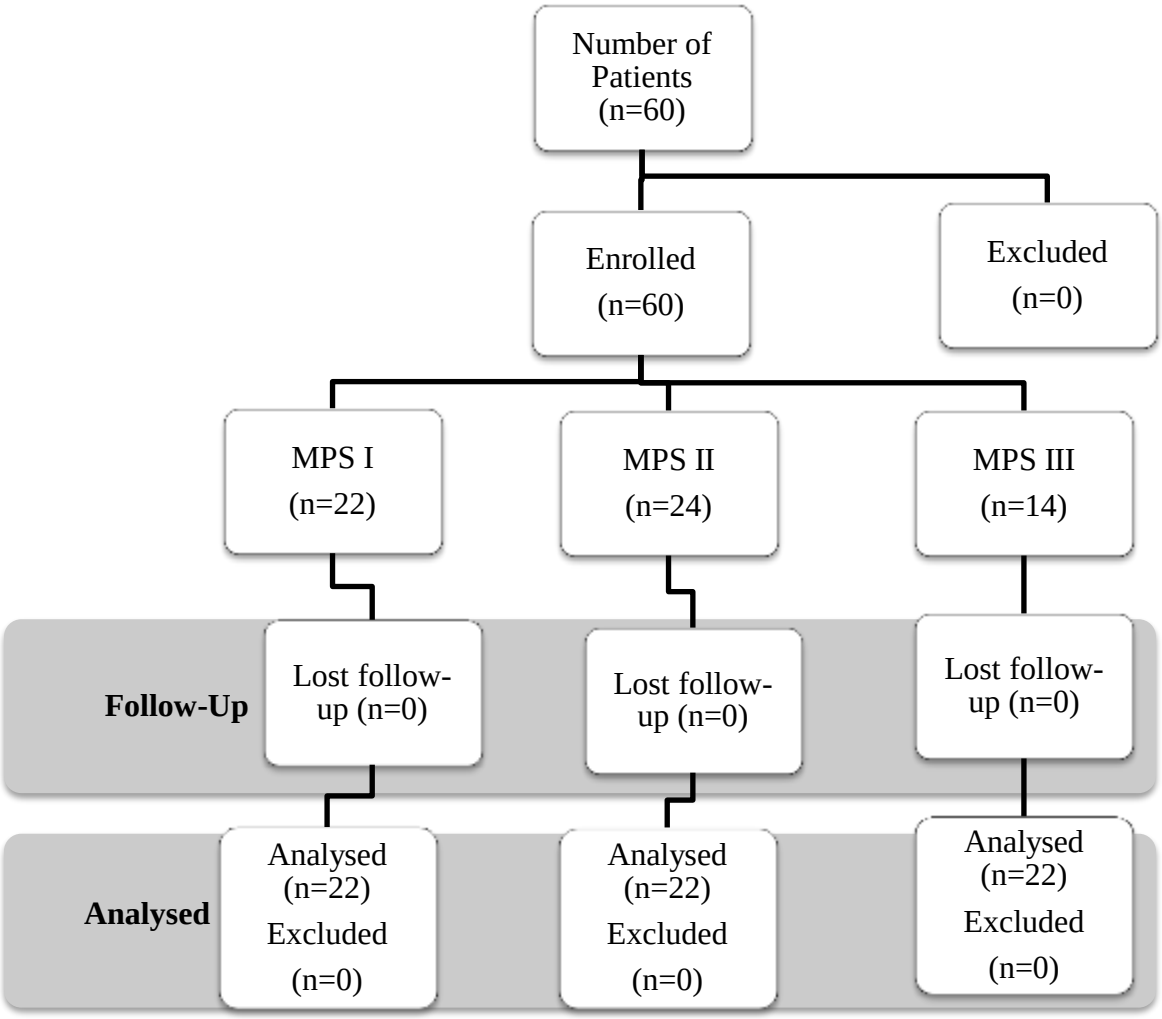

Table 1: Demographic characteristics of the patients

S. No.	Parameter	Value
1.	ASA Physical Status	
	I	44
	II	16
2.	Age(years), mean (SD)	48.50 + 13.23
3.	BMI (kg/m^2). Mean (SD)	24.46 + 2.912
4.	Gender (n)	
	Males : Females	15 : 45
5.	Surgery	
	Lap Cholecystectomy	36
	FESS	10

	MRM	10
	Ortho Limb Surgery	14

SD- Standard Deviation; ASA- American Society of Anesthesiologists; BMI- Body Mass Index

Table 2: Descriptive statistics regarding performance characteristics of BLOCKBUSTER LMA

S. No.	Parameter	Value
1.	Blockbuster Size (n)	
	3	42
	4	12
2.	Ease of Insertion	
	1 = No Resistance	58
	2 = Moderate Resistance	2
	3 = High Resistance	0
	4 = Not able to place the device	0
3.	Time taken for Insertion, Mean (SD)	14.2 + 4.8 sec
4.	Ease of ETT Insertion	
	1st Attempt	55
	2nd Attempt	4
	3rd Attempt	0
	Not Passed	1
5.	Time for ETT Insertion	11.7 + 5.4 sec
6.	Ease of Gastric Tube Insertion	
	Passed Easily	56
	Passed with Resistance	4
	Not Passed	0
7.	Leak Pressure	33.2 + 2.2
8.	Ease of Blockbuster Removal	
	Easy Removal	60
	Difficulty in removal	0
9.	Time taken for removal of LMA	14.6 + 7.2

LMA- Laryngeal Mask Airway; ETT- Endotracheal Tube; SD- Standard Deviation

Table 3: Complications

S. No.	Complications	Number of Patients
1.	Blood on Device	0
2.	Laryngospasm	0
3.	Bronchospasm	0
4.	Desaturation	0
5.	Cuff Rupture	0

ISSN 2515-8260 Volume 10, Issue 03, 2023

Table 4: Hemodynamic Changes

S. No.	Parameter	Value
1.	Mean Heart Rate	85 + 12
2.	Mean Systolic Blood Pressure	118 + 12
3.	Mean Diastolic Blood Pressure	78 + 6
4.	Blood Oxygen Saturation	98-100%

Table 5: Post Operative Complications

S. No.	Parameter	Immediate	1st Hour	4th Hour	8th Hour
1.	Sore Throat				
	1 = None	52	0	0	0
	2 = Mild	6	0	0	0
	3 = Moderate	2	0	0	0
	4 = Severe	0	0	0	0
2.	Hoarseness	8	0	0	0
3.	Nausea	3	0	0	0
4.	Vomiting				
	1 = None	0	0	0	0
	2 = Mild	0	0	0	0
	3 = Moderate	0	0	0	0
	4 = Severe	0	0	0	0

Discussion

Safely securing the airway in a patient during the operative period is the lifeline of modern anesthesia practice. The Blockbuster LMA is the latest addition to the family of intubating LMA's. In very limited studies on the Blockbuster LMA, the device has shown great results during intubation through it while using the Blockbuster tube.

In our study, the main finding was that the Blockbuster LMA can be an adequate ventilating device in terms of insertion and ventilating features, showing an overall 100% insertion rate with timeframes comparable to other SGD's. [10] However, when assessed as a conduit for intubation, it also performed significantly high with a success rate of 98.33% which is significantly higher when we compare the study of Yunluo *et al.* [11]

To the best of our knowledge, we found no observational studies which evaluated the safety and efficacy of the Blockbuster LMA.

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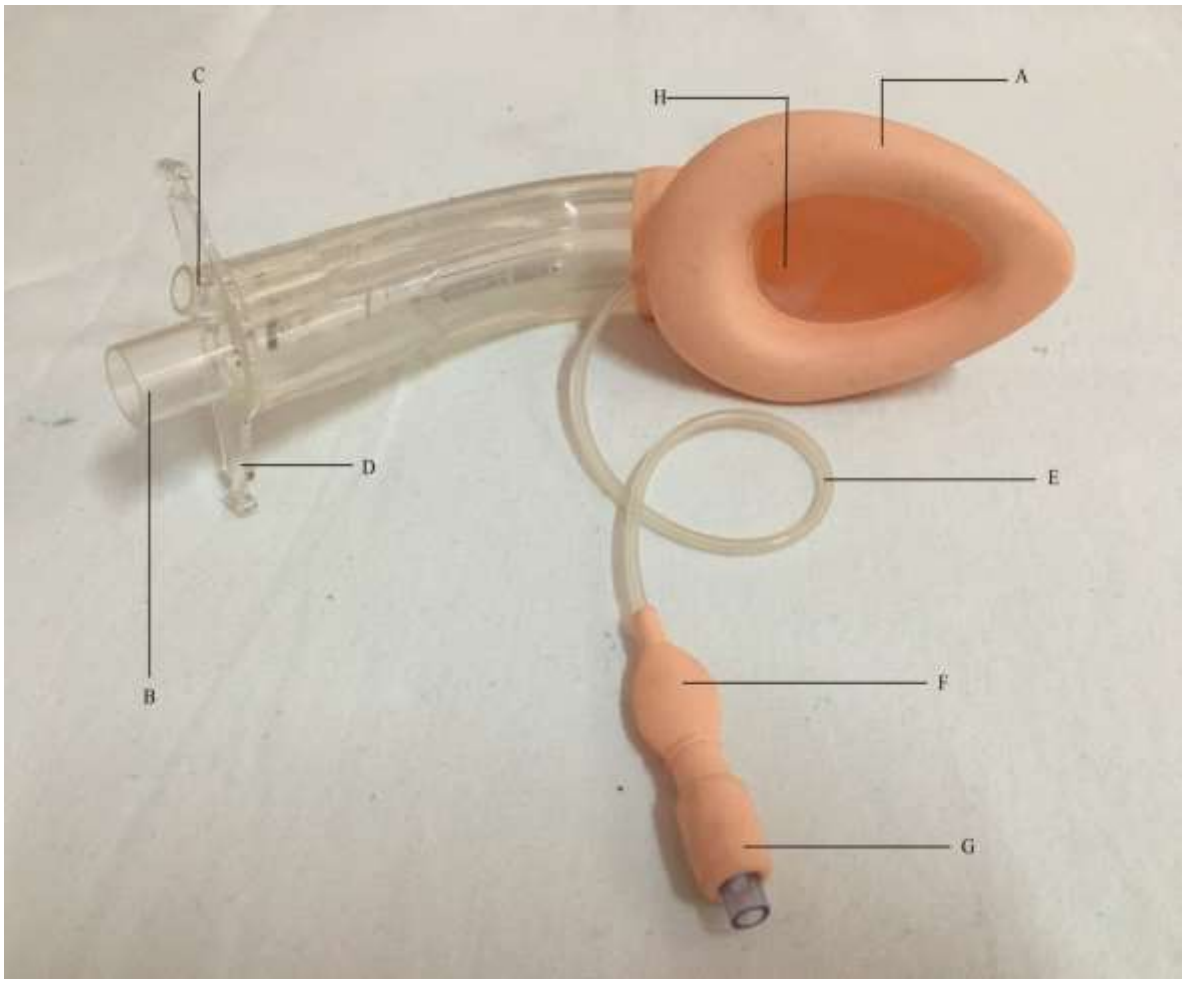

Figure 2: **A-** Mask; **B-** Airway; **C-** Gastric Access Channel; **D-** Four-way Connector; **E-** Inflation Line; **F-** Inflation Pilot Balloon; **G-** Check Valve; **H-** ET Tube Guide Device.

We achieved such high success rate of intubation through the Blockbuster LMA because of its appropriate anatomy and alignment. The airway tube of the LMA is >95° angulated and relatively short. This aligns perfectly with the oropharyngeal curve [Figure 3]. The inverted tip of the Blockbuster tube [Figure 5] helps in overcoming the impingement of the tube to the tracheal wall during intubation. The parker flexi tip of the tube helps it to find a way in the least resistant areas. Another advantage of this tube is that the angle made by the Blockbuster tube while coming out of the cuff is around 30° [Figure 4] [Figure 5] [Figure 6].

ISSN 2515-8260 Volume 10, Issue 03, 2023

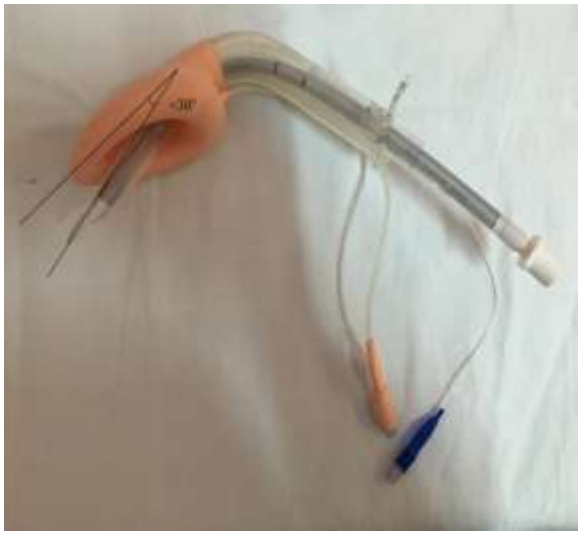

Figure-3

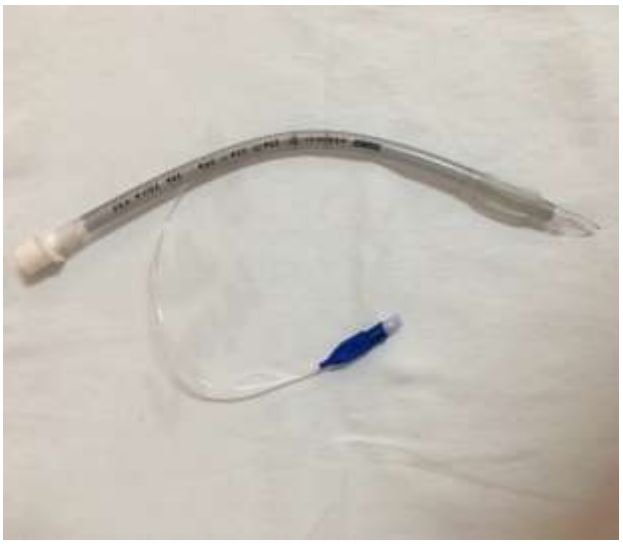

Figure-4

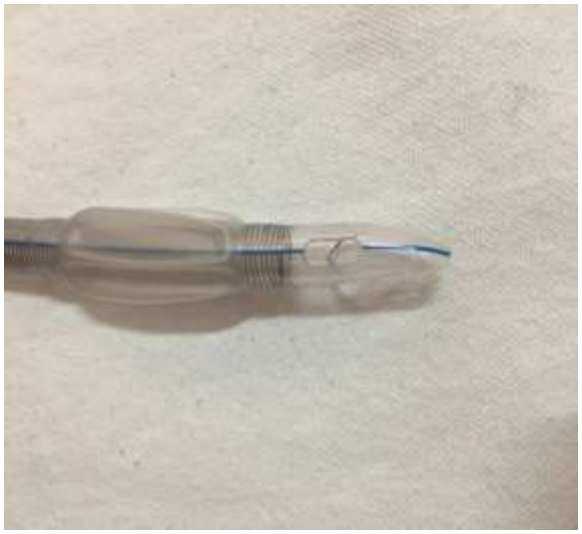

Figure-5

Figure-6

ISSN 2515-8260 Volume 10, Issue 03, 2023

Figure-7

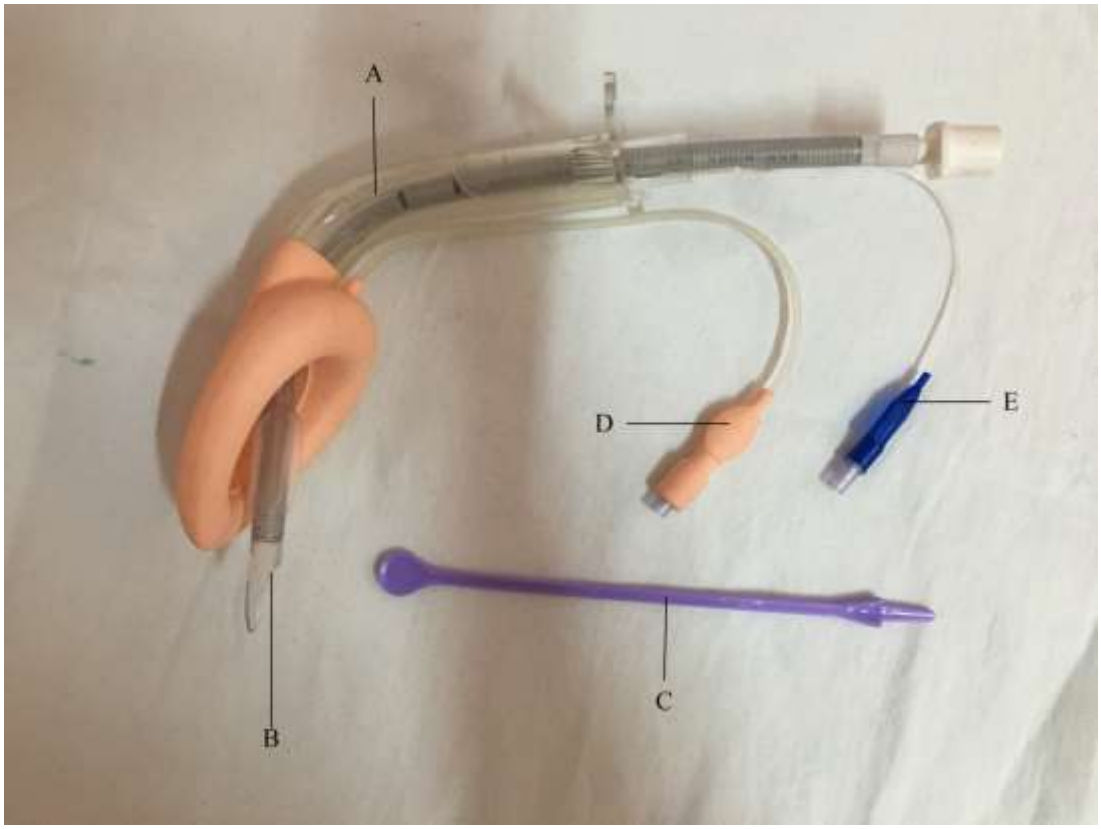

Figure 8: A- Blockbuster LMA; B- Blockbuster Tube; C- Stabilising Rod; D- Pilot Baloon; E- Inflatable Cuff of the ETT

There was significantly less time used for intubation with this device. The reason for this is clearly based on the unique shape and anatomical alignment of the LMA, along with a short airway tube. Our results coincide with previous studies. [11, 12, 13, 14]

We use oropharyngeal seal pressure as a marker for depicting the quality of the airway seal. This is clinically significant because higher seal pressures produced by such devices provide higher and better peak inspiratory pressures which further aid in positive pressure ventilation. The

Blockbuster LMA demonstrated higher seal pressures. These results were similar to previous studies. [11, 15, 16] The reason for this device to provide a higher seal pressure is that, it has an additional dorsal cuff which improves the seal ability and also reduces the risk of aspiration [Figure 7].

The complications included in the supraglottic injury score like sore throat were negligible because the Blockbuster tube exerted low resistance during its passage causing reduced mucosal injury. The results we found were similar to the study conducted by Su K *et al.* [16]

The Blockbuster LMA is the upcoming preferred choice for airway management as it provides a quick and reliable security of the airway with a good sealing capacity, also making it useful for positive pressure ventilation. The less pharyngeal stimulation caused by it causes lesser complications. Additionally, the Blockbuster LMA has a smooth extubation capability which helps in safer extubation and fewer complications. The Blockbuster LMA has a better airway dynamic profile and a better hemodynamic profile as is shown in our study.

The significance of this study is that although we did blind intubation in patients with normal airway, we confirmed the safety and efficacy of the device in the peri-operative and post-operative period after performing randomization and blinding procedures for patient selection.

The limitations of our study are that firstly, we have a smaller sample size. We need a bigger sample size to confirm the outcomes. The second limitation is that we have studied patients with normal airway anatomy instead of patients with difficult airways, where an SGD is more likely to be used. However, the lack of evidence for the use of the Blockbuster LMA in securing an airway of a normal patient prevented its use in known difficult airways. Thirdly, we have not compared our device with any established SGD because our primary aim was to evaluate the feasibility of the device to work as a conduit for intubation. However, we conducted our study in accordance with other studies where a newer SGD was evaluated for its clinical utility. [17, 18, 19, 20, 21, 22] Our aim here was to do a stage two study, which is required to evaluate the safety and efficacy of the LMA to be used for intubation, as per the recommendations for studying the newer SGD's. [23] Further prospective randomized control trials are needed to compare the device with other established second-generation SGD's keeping in view the ADEPT guidelines of Difficult Airway Society. [24]

We found no conflicts of interest in our study.

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