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A CLINICAL COMPARATIVE STUDY OF ENDOTRACHEAL INTUBATION THROUGH INTUBATING LARYNGEAL MASK AIRWAY – FASTRACH™ VERSUS BLOCKBUSTER™

Anaesthesiology

Dr. Neelam Singh Professor And Head Of Department Anaesthesiology And Critical Care , Moti Lal Nehru Medical College , Prayagraj , U.P.

Dr. Dharmendra Kumar Yadav Associate Professor , Department Of Anaesthesiology And Critical Care , Moti Lal Nehru Medical College , Prayagraj , U.P.

Dr. Apala Shanker Garg* Junior Resident , Department Of Anaesthesiology And Critical Care , Moti Lal Nehru Medical College , Prayagraj , U.P. *Corresponding Author

ABSTRACT

Background : Supraglottic airway devices(SAD) are useful airway adjuncts in managing difficult airway and can be used as a conduit for blind endotracheal intubation

AIM : This randomized study was undertaken to evaluate the success rate of blind intubation using BlockBuster™ and Fastrach™ laryngeal mask airway .

Material and Methods : Ninety six patients of both sexes, aged between 18-65 years and belonging to ASA class I and II undergoing surgical procedures under general anaesthesia were randomly divided into two groups F and B (F- Fastrach, B- BlockBuster) of equal number. Following induction the allocated device was inserted and after confirming adequate ventilation, blind endotracheal (ET) intubation was attempted through the device.

Observation: Time taken for SAD insertion , First attempt and overall success rate of SAD insertion and ET intubation through SAD; hemodynamic changes and postoperative complications were recorded and compared between groups.

Result : Demographic profile, success rate of SAD insertion, and adverse effects were similar between groups ($p>0.05$). The overall success rate of intubation was 95.8% in Group F and 83.3% in Group B ($P = 0.045$) . The mean time for intubation was 37.19±51.75 sec in group B 16.47±17.21 sec in Group F . ($p=0.012$)

Conclusion : We concluded that laryngeal mask airway (LMA) Fastrach™ provides higher first pass success rate of blind tracheal intubation and better haemodynamic stability than LMA BlockBuster™

KEYWORDS

LMA , ET, SAD

INTRODUCTION

General anaesthesia is associated with various effects on the respiratory system, including the loss of airway patency, protective airway reflexes, hypoventilation and apnea. Therefore, one of the fundamental responsibilities of an anaesthesiologist is to ensure adequate ventilation and oxygenation. Tracheal intubation is considered as the gold standard for securing airway, which prevents pulmonary aspiration along with providing stable ventilation.[1] Supraglottic airway devices with a conduit for blind tracheal intubation are a bridge connecting ventilation and intubation [2] . But to protect the airway from aspiration, blind endotracheal intubation with a SAD is required [3]. The Fastrach™ LMA, invented in 1997 (Teleflex medical, Ireland) has a single moveable epiglottis elevating bar, a guiding "V" shaped ramp for guiding the emerging endotracheal tube towards the glottis. Endotracheal tube with an armored silicone tip is the best for intubation through LMA Fastrach™ .[4]

Touren's BlockBuster™ LMA invented in 2012 (Tuorenmedical instrument co. Ltd, China) is by Professor Dr. Ming Tian, and it provides ventilation , increases the green channel for intubation [5].

A silicone wire reinforced tube with a Touhy-tip named as the BlockBuster™tube, is recommended for intubation via the BlockBuster™ LMA. This tube has a soft, flexible, blunt edge that causes less mucosal damage during blind intubation. There are studies which suggest rate of successful blind intubation through BlockBuster™ LMA in patients to be 90-95%.[6] This LMA has some unique features like its 95-degree angulated airway that makes ventilation and intubation easier through it. It also has a gastric port and provides better sealing pressures at low volumes. The unique tip of the Parker Flexi Tip Tube prefers non-resistant areas which makes it easier to perform intubation[7].

The purpose of this study is to compare the success rate of blind endotracheal intubation through LMA BlockBuster™ and LMA Fastrach™. Secondary outcomes that will be assessed in this study are ease of intubation using both the LMA devices, the time taken for successful intubation, total number of intubation attempts required for successful intubation along with time taken for removal of device after intubation. Various complications of using the LMA devices and endotracheal will be noted at regular intervals of time.

Figure 1: BlockBuster LMA with ET tube

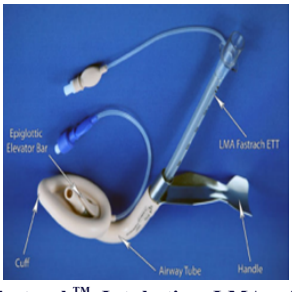

Figure 2:The Fastrach™ Intubating LMA with its reusable endotracheal tube in situ and components

MATERIALS AND METHODS

STUDY SETTING:

The present study was carried out in the Department of Anaesthesiology, at Moti Lal Nehru Medical College and Associated Swaroop Rani Nehru Hospital, Prayagraj (Allahabad) over a period of one year from july 2020 to july 2021 after approval from institutional ethical committee and obtaining written and informed consent from all the patients.

The study is a Prospective, Single blinded, Randomised clinical trial. (Dichotomous end point, two independent sample study) carried out on 96 adult patients(48 patients in each group) of either sex aged between 18 to 65 years belonging to American society of Anaesthesiologists (ASA) physical status I & II, having stable cardiovascular status, posted for elective surgeries under general anesthesia.

INCLUSION CRITERIA :
- Age 18-65 yrs
- ASA class I & II
- Patients of either sex
- MPG grade I &II
- Patients undergoing elective surgeries under general anaesthesia

EXCLUSION CRITERIA:
- Patients not giving consent for study
- Pregnant patients
- ASA class III & IV
- Patients with loose dentures
- MPG grade III & IV
- Contraindications to LMA insertion such as Reflux disease

GROUPALLOCATION
- Patients were randomly allocated and divided into two groups (48 patients each) according to the type of Laryngeal Mask Airway device being used to intubate the patient.

Group B	BLOCKBUSTER LMA	48 patients
Group F	FASTTRACH LMA	48 patients

STATISTICALANALYSIS:
Data was entered into MS-Excel and analyzed in SPSSV22 software. Independent t- test / Mann-Whitney U test, Chi square test / Fisher exact test were calculated. Clinical observation with p value <0.05 was taken as significant.

METHODOLOGY
A detailed Pre-Anesthetic evaluation was done one day before surgery. All the patients were given 0.25 mg tablet of alprazolam and tablet rantidine (150 mg) orally one night before surgery. Patients were kept nil by mouth 8 hours prior to surgery A standardized protocol for general anesthesia was followed for all patients After arrival of patient in the operating room, 18G or 20G peripheral intravenous cannula was inserted. Standard multipara monitoring was used : NIBP (non invasive Blood Pressure), ECG (Electrocardiogram), pulse-oximeter, End tidal carbon dioxide ($EtCO_2$).

Premedication done with iv inj.Glycopyrrolate 0.2 mg, iv Ondansetron 4 mg, inj. Midazolam 0.02 mg/kg, inj. Fentany l – 2 mcg/kg`.

Pre-oxygenation for 3 minutes with 100 percent Oxygen and anaesthesia induced with intravenous Propofol (2 mg / kg) in running drip and adequacy of mask ventilation noted.

After confirming adequate mask ventilation vecuronium 0.1 mg/kg administered for neuromuscular blockade.After 3 minutes, either of the devices was inserted using midline insertion technique in neutral neck position for both the groups.Appropriate size of LMA size was used i.e. size 3 (30 to 50 kg), size 4 (50 to 70 kg), size 5 (70 to 100 kg).

Adequate ventilation confirmed with chest movements and end tidal carbon dioxide waveforms.

The patient were ventilated with a mixture of oxygen, nitrous oxide and isoflurane (1%) Time required for the insertion of LMA defined as time from removal of facemask to time where adequate ventilation as established through LMA with normal square wave capnogram.

Adequate ventilation is defined by easy bag mask ventilation, bilateral equal air entry, absence of audible leak around the cuff.After insertion of the LMA cuff was inflated to a pressure of 60 cm of water (Maximum 30 ml air) LMA was connected to the breathing circuit. Number of attempts for LMA insertion were noted The time for successful tracheal intubation started when endotracheal tube was inserted into the green channel of LMA until confirmation through capnographic waveform and equal bilateral air entry.

Intubation was performed blindly through the LMA using LMA specific tubes:

Anaesthesia maintained with 0.5 to 1 % Isoflurane, 66 % nitrous oxide, 33 % oxygen, vecuronium bromide.

The number of intubation attempts were limited to three.

After successful intubation, LMA was removed using standard technique and stabilizing rod.

At the end of the surgical procedure, neuromuscular blockade was reversed with inj. Neostigmine 0.05mg per kg and inj. Glycopyrrolate 0.02 mg per kg body weight.Once the patient was awake or easily arousable with vocal commands, the patient was safely extubated and oxygen mask was placed.

Post-operative complications like sore throat, cough, nausea, hoarseness recorded in the postoperative period after extubation.

OBSERVATIONS :
The following observations were drawn from our study

Table 1 :Intergroup Comparison of demographic profile

PARAMETERS	Group-B	Group-F	P-Value
AGE (years) (mean ± SD)	37.27±10.80	40.81±9.27	0.088
Sex (F/M)	23 (47.9%) 25 (52.11)	26 (54.2%) 22 (45.81)	0.540
Weight (Kg) (mean ± SD)	66.94±8.85	67.08±7.96	0.933
Height (cm) (mean ± SD)	166.04±9.63	165.5±9.33	0.780
BMI(kg/m^2) (mean ± SD)	24.59±4.71	24.48±3.51	0.901
ASA Class I Class II	 60.4% 39.6%	 52.1 47.9	 0.411
MPG Grade 1 Grade 2	 54.2% 45.8 %	 62.5 % 37.5 %	 0.408

Table 2 : Intergroup Comparison of Mean Arterial Pressure

MAP	Group BlockBuster		Group Fastrach		t-value	p-value
	Mean	SD	Mean	SD		
Pre-Operative	90.17	6.54	91.85	7.17	-1.20	0.234
During LMA Insertion	94.97	5.73	94.13	6.23	0.68	0.498
After LMA Insertion	99.79	5.03	95.83	5.73	3.61	**0.001**
During Et Intubation	105.57	5.17	96.96	5.25	8.09	**<.001**
After ET intubation 1 min	109.72	4.86	95.70	4.95	14.00	**<.001**
After ET intubation 5 min	105.76	5.87	93.30	4.77	11.41	**<.001**
After ET intubation 10 min	99.97	5.60	91.76	5.54	7.22	**<.001**

Table 3 :Intergroup Comparison of Heart Rate

Heart Rate	Group BlockBuster		Group Fastrach		t-value	p-value
	Mean	SD	Mean	SD		
Pre-Operative	76.90	9.18	77.02	9.33	-0.07	0.947
During LMA Insertion	82.29	9.28	80.23	9.43	1.08	0.283
After LMA Insertion	87.54	9.54	83.33	9.63	2.15	**0.034**
During Et Intubation	93.00	10.17	85.15	9.42	3.92	**<0.001**
After ET intubation 1 min	92.75	9.49	83.27	9.73	4.83	**<0.001**
After ET intubation 5 min	87.08	8.58	80.56	9.78	3.47	**0.001**
After ET intubation 10 min	82.40	8.26	78.27	9.11	2.32	**0.022**

Table 4 :Intergroup Comparison of Time Taken for LMA Placement and Intubation

Time taken total	Group BlockBuster		Group Fastrach		t-value	p-value
	Mean	SD	Mean	SD		
LMA Placement (Seconds)	39.04	55.21	34.15	51.93	0.45	0.656
Intubation (Seconds)	37.19	51.75	16.47	17.21	2.56	**0.012**

Table 5 :Intergroup Comparison of Number of Attempts for LMA Placement and Intubation

Number of attempts		Group BlockBuster		Group Fastrach		chi sq	p-value
		No.	%	No.	%		
LMA Placement	One	35	72.9%	39	81.3%	2.08	0.354
	Two	9	18.8%	8	16.7%		
	Three	4	8.3%	1	2.1%		
Intubation	One	34	70.8%	38	79.2%	6.27	**0.044**
	Two	6	12.5%	9	18.8%		
	Three	8	16.7%	1	2.1%		

Table 6 :Intergroup Comparison of successful intubation

Intubation		Group BlockBuster		Group Fastrach		chi sq	p-value
		No.	%	No.	%		
Successful	No	8	16.7%	2	4.2%	4.02	**0.045**
	Yes	40	83.3%	46	95.8%		

Table 7 : Intergroup Comparison of Post-Operative Complications

Post-Operative Complications	Group BlockBuster		Group Fastrach		chi sq	p-value
	No.	%	No.	%		
Laryngospasm	0	0.0%	0	0.0%	NA	NA
Sore throat	13	27.1%	7	14.6%	2.27	0.132
Nausea and Vomiting	5	10.4%	4	8.3%	0.12	0.726
Cough	2	4.2%	3	6.3%	0.21	0.646
Hoarseness	1	2.1%	1	2.1%	0.00	1.000
Aspiration	0	0.0%	0	0.0%	NA	NA
Blood Staining	14	29.2%	11	22.9%	0.49	0.485
Haemodynamic Instability	0	0.0%	1	2.1%	1.01	0.315

No significant difference was found in mean EtCO2 and SPO2 between the groups at any time during the procedure (p>0.05).

RESULT :

Demographic data was comparable between the two groups with respect to age, sex , weight , height ,BMI , ASA status , Mallampati grade with no significant difference . (p> 0.05)

Significant difference was found in mean MAP between the groups After LMA insertion (p=0.001), during ET intubation (p<0.001) and after ET intubation (p<0.001).

Significant difference was found in mean Heart rate between the groups After LMA insertion (p=0.034), during ET intubation (p<0.001), after ET intubation 1 min (p<0.001), 5 min (p=0.001) and 10 min (p=0.022)

LMA Fastrach showed lesser fluctuations in MAP and HR as compared to LMA BlockBuster ,sh showing more stable haemodynamics .

No significant difference was found in mean $EtCO_2$ and SPO_2 between the groups at any time during the procedure (p>0.05).

The mean time taken for intubation in Group BlockBuster was 37.19±51.75 sec while the mean time taken for intubation in Group Fastrach was 16.47±17.21 sec. Significant difference was found in mean time taken for intubation between the groups (p=**0.012**)

The number of attempts for intubation in group BlockBuster were one, two and three in proportion 70.8%, 12.5% and 16.7% respectively while for Group Fastrach they were in proportion 79.2%, 18.8% and 2.1% respectively. Significant difference was found in number of attempts for intubation between the groups (p=0.044).

The number of successful intubation in Group BlockBuster and Group Fastrach was 83.3% and 95.8% respectively. Significant difference was found in number of successful intubation between the groups (p=**0.045**).

No significant difference was found in any of the post-operative complications between the groups. However more proportion of complications was observed in Group BlockBuster.

DISCUSSION

Since the introduction of LMA into clinical practice has been used in over a million patients and the efficacy is proven beyond doubt. The improvisation of the existing devices also paved a way to many researches creating in new ideas and thereby newer supraglottic devices. The LMA Fastrach™ airway is an advanced type of SGAD, especially designed to facilitate tracheal intubation with an endotracheal tube (ETT). It permits single-handed insertion with the head and neck in a neutral position . Introducing the intubating laryngeal mask Fastrach in 1997 was a milestone in modern airway management. LMA Fastrach was considered as “gold standard” for laryngeal mask guided intubation.

ArchanaEndigeri et al [2]The first-attempt success rate of tracheal intubation was 90% in Group B and 66.6% in Group F (P = 0.028), while the overall success rate of intubation was 96.6% in Group B and 89.9% in Group F (P = 0.3). Complications such as sore throat and blood stain were reduced with BlockBuster® LMA. The time for LMA removal after intubation was significantly less in Group B (33.0 ± 2.1s) when compared to Group F (45.1 ± 4.4s), P = 0.001

Dr.Smita Joshi et al[8] The success rate of intubation using FASTTRACH ILMA was 96.67% in their pilot study. No laryngoscopy required and no manipulation of head needed are strong advantages that render FASTTRACH ILMA superiority over other supraglottic airway devices and also make it a rational alternative to primary intubating devices for blind endotracheal intubation in patients with normal airway

Lakesh A. et al[9]concluded that Fastrach LMA had a higher success rate in facilitating blind tracheal intubation as compared with Ambu Aura–I.

HimanshuSagar et al [10]concluded that the mean Time taken for Endo-tracheal Tube was significantly more among I-gel (24.00±0.31) minutes in comparison to LMA FASTTRACH (19.95±0.37).

Sameer Kapoor et al [11]inferred the success rate of tracheal intubation in first attempt was 66% with I gel and 74% with LMA Fastrach, while the overall success rate of tracheal intubation was 82% with, I gel and 96% with LMA Fastrach. The time taken for successful tracheal intubation through LMA Fastrach was lesser (20.96 s) when compared with I gel (24.04 s).

Yunluo LY et al [12]et al concluded that as compared with Proseal LMA, BlockBuster LMA had advantages such as in in providing better hyper larynx ventilation and increasing the green channel for intubation.

CONCLUSION

To conclude, LMA Fastrach was better than LMA BlockBuster in terms of safety and effectiveness in controlling upper airway during general anaesthesia. There was a higher first pass successful intubation rate and lesser number of attempts were needed to intubate using LMA Fastrach. Hemodynamic instability occurred more with LMA BlockBuster. Post-operative complications were comparable in both the groups. Present study showed that LMA Fastrach and LMA BlockBuster both can be used as airway management devices however, LMA Fastrach is a better conduit for blind endotracheal intubation as compared to LMA BlockBuster.

Limitations of the study :

oropharyngeal seal pressure measurement, and fibreropticglottic visualization score was not performed due to unavailibilty of device .

Haemodynamically unstable patients undergoing emergency surgeries and pregnant patients were not included in the study.

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