Original Article

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A Comparison of Tracheal Intubation with Ambu® AuraGain™, Fastrach® and BlockBuster® Laryngeal Mask Airway: A Randomised Clinical Trial

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ABSTRACT

Introduction: Airway management has been a key to quality, efficacy and safety of anaesthesia. The Ambu® AuraGain™ is an anatomically curved Supraglottic Airway Device (SAD), which has gastric access port and is used for both ventilation and endotracheal intubation. Fastrach® Intubating Laryngeal Mask Airway (FT-LMA) serves as a conduit for intubation and ventilation for difficult airway situation. It has an epiglottic elevating bar designed to lift the epiglottis as endotracheal tube passes. BlockBuster® LMA is latest generation LMA used for ventilation and intubation. It has a short airway tube which has >95° angulation to match the oropharyngeal curve and thus makes the insertion easy and less traumatic.

Aim: To compare first attempt success rate of tracheal intubation using Ambu® AuraGain™, Fastrach® and BlockBuster® LMA in adult patients.

Materials and Methods: The present randomised clinical trial was conducted in the Department of Anaesthesiology, Ravindra Nath Tagore Medical College, Udaipur, Rajasthan, India, from February 2021 to February 2022. The study comprised of 135 American Society of Anesthesiologists (ASA) physical status I and II patients of both sex, aged 18-60 years who were admitted and scheduled for elective surgery requiring general anaesthesia and tracheal intubation. The patients were randomly assigned into three groups (45 in each)- group A (Ambu® AuraGain™ group), group F (Fastrach® group), and group B (BlockBuster® group). Tracheal intubation was performed using appropriate size endotracheal tube after LMA placement. The outcome measures were first attempt successful intubation, time taken for intubation, glottis visualisation and incidence of complications (blood stained LMA, nausea/vomiting).

Results: The mean age of the group A, group B and group F were 35.8±15.0, 32.71±12.59, and 38.7±14.7 respectively which was statistically not significant. Group B had a significantly greater success rate of first attempt intubation (93.3%) in comparison with group F (64.4%) and group A (22.2%). LMA insertion score of 1 was found in 53.3% patients in group B, 42.2% patients in group F and 15.5% patients in group A. A Brimacombe score of 4 was found in 46.6% patients in group B as compared to 13.3% patients in group F and (33.3%) patients in group A, (p-value=0.020). Blood stained LMA was found in 1 patient in group B, 9 in group F and 7 in group A (p-value=0.030).

Conclusion: BlockBuster® LMA is a better conduit for tracheal intubation than Fastrach® LMA and Ambu® AuraGain™ in adult patients with no anticipated airway difficulties.

Keywords: Endotracheal intubation, Supraglottic airway devices, Ventilation

INTRODUCTION

Airway management remains a vital primary skill for anaesthetist. In the events of failure to intubate and failure to ventilate, LMA play a critical role [1]. LMA are inserted upto glottic entry via oral route and can be used in conditions when tracheal intubations and mask ventilations are challenging [2]. LMA is a SAD developed way back in 1981 by Dr. Archie brain [3,4]. Many devices and instruments have been introduced and used to make intubation an easier and simple technique. Ambu® AuraGain™, Fastrach®, and BlockBuster® LMA are some of the newly introduced LMAs.

The Ambu® AuraGain™ is a single use, phthalate free-Polyvinyl Chloride (PVC) material made, anatomically curved SAD, which is designed for both ventilation and as a conduit for tracheal intubation. It incorporates a 90° preformed curvature designed to approximate airway anatomy, bite block and has navigation marks to guide a fiberscope during intubation. The thin and soft cuff of the Ambu® AuraGain™ is designed to deliver high seal pressures-documented upto 40 cm H_2O. Fastrach®, LMA consists of mask with a surrounding inflatable bag compatible with the shape of hypopharynx and a tube that has 30° angle with mask [3-7]. It has a short and curved stainless steel shaft (15 mm connector) for allowing the insertion of the tube and its cuff to pass beyond the vocal cords. It consists of an epiglottic elevating bar which lifts the epiglottis when the tracheal tube is passed [7]. Blockbuster® LMA is made up of soft and pliable silicone to avoid trauma. It has a short airway tube which has >95° angulation to match the oropharyngeal curve and thus makes the insertion easy and less traumatic. It has a guidance device which directs the tracheal tube towards the laryngeal opening at an angle of 30° which enhances rate of successful blind intubation [8].

However, to the best of our knowledge, there is no study comparing the three devices together i.e. Ambu® AuraGain™, Fastrach® LMA and BlockBuster® LMA. Hence, present study was conducted to compare success of tracheal intubation using Ambu® AuraGain™, Fastrach® and BlockBuster® LMA in adult patients. The primary outcome measure was first attempt success rate of tracheal intubation. The secondary outcome measures were ease of LMA insertion, oropharyngeal seal pressure, time taken for intubation, fiberoptic grade of laryngeal view, to evaluate the impact on haemodynamic variables and adverse events/complications if any.

MATERIALS AND METHODS

The present randomised clinical study was conducted in the Department of Anaesthesiology, Ravindra Nath Tagore Medical College, Udaipur, Rajasthan, India, from February 2021 to February 2022. The Institutional Ethical Committee approval was obtained [RNT/Stat./IEC/2020/05], and the study was registered with Clinical

Trial Registry of India (CTRI) [CTRI/2021/08/035399] for one year and written informed consent was taken from each patient.

The cases included in the study were of Ear, Nose and Throat surgeries, general surgical, neurosurgical and gynaecological surgical procedures.The study procedures were performed by three experienced anaesthesiologist. All patients under the study were subjected to a detailed preanaesthetic evaluation, to rule out any anatomical or systemic disorders and for airway assessment. All the routine and relevant investigations were performed during the evaluation.

Inclusion criteria: Patients with American Society of Anesthesiologists (ASA) grade I and II of both sex and aged between 18-60 years were included in the study. Total 135 patients following the above criteria were admitted, posted for surgery, requiring general anaesthesia and endotracheal intubation were included.

Exclusion criteria: Patient with uncontrolled hypertension, cardiac disease, upper respiratory infections, renal and hepatic failure or impairment, Body Mass Index (BMI) >30 kg/m^2, mouth opening <2.5 cm, patients with risk of gastric aspiration i.e. in patients with BMI >30 kg/m^2, history of hiatus hernia, pregnant women, an anticipated difficult intubation during preanaesthetic evaluation were excluded.

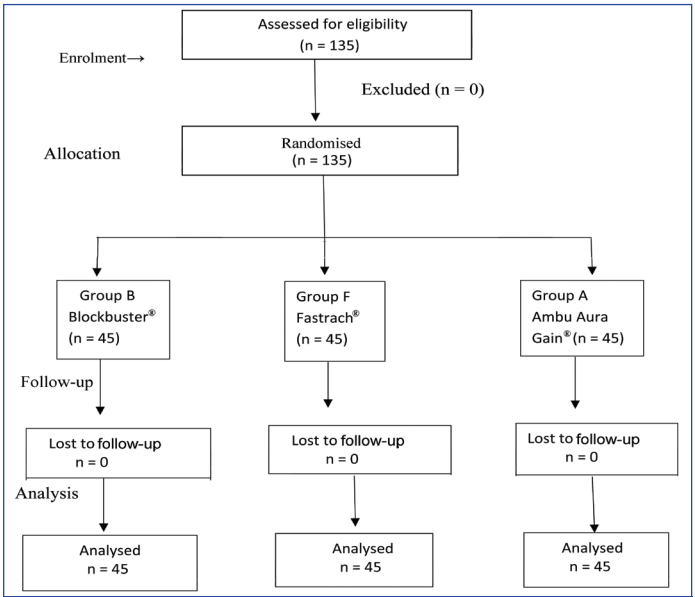
Sample size calculation: Sample size was calculated on the basis of the study by Schiewe R et al., where tracheal intubation time was 14.15+4.4 secs versus 21.3+9.0 secs (mean difference=7.2) with Fastrach® and Ambu® AuraGain™, respectively [9]. Using the Epi Info software, the sample size is calculated considering the mean difference of time for tracheal intubation as 7.2, confidence interval of 90%, power 80%. A sample size of 42, in each group, was required. To compensate for drop outs, 45 patients in each group was considered, making a total of 135 patients.

Study Procedure

Patients were randomly assigned to one of the three groups (45 patients in each group) by using computer generated random numbers.

Group allocation:

- Group A (Ambu® AuraGain™ group): Tracheal intubation performed using appropriate size endotracheal tube after Ambu® AuraGain™ LMA placement.
- Group F (Fastrach® group): Tracheal intubation performed using appropriate size endotracheal tube after LMA Fastrach® placement.
- Group B (BlockBuster® group): Tracheal intubation performed using appropriate size endotracheal tube after BlockBuster® LMA placement [Table/Fig-1].



[Table/Fig-1]: CONSORT flowchart.

Anaesthesia Technique

All the patients were instructed for overnight fasting. One night before surgery tab. alprazolam 0.25 mg was given. Chlorhexidine mouthwash was done by patients in the morning. Capsule omeprazole 20 mg was taken by the patients two hours before surgery.

On arrival to the operation room, standard monitoring (pulse oximeter, non invasive blood pressure and electrocardiogram) were applied and the patient's baseline vitals [Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) and Peripheral Oxygen Saturation (SpO_2)] were noted. A peripheral intravenous line with 18G cannula was secured and an infusion of ringer lactate was started at rate of 8 mL/min. Patients were premedicated with inj. glycopyrrolate (0.01 mg/kg), inj. ondansetron (0.1 mg/kg), inj. midazolam (0.05 mg/kg) and inj. fentanyl (2 mcg/kg) intravenously. Patients were preoxygenated for three minutes with 100% O_2 and induction done with inj. thiopentone (5-6 mg/kg).

Adequate mask ventilation was performed and after that inj. vecuronium 0.1 mg/kg was administered and three minutes later, an adequate size LMA device was inserted by using a midline insertion method in all the groups. According to the body weight, size of LMA is selected [size 3 for (30-50 kg) and size 4 for (50-70 kg) as per the manufacturers' guidelines]. Lung ventilation was done with a mixture of oxygen and sevoflurane (2%). After the insertion, LMA cuff was inflated with air with the help of Smiths cuff pressure manometer (Smiths Medical International Ltd. Boundary Road, Hythe, KentCT216JL, UK). Breathing circuit was then connected to the LMA. Chest movements and square wave capnogram were used to confirm the adequate ventilation.

Assessment of parameters: A subjective scale of 1-4 is used for assessing the number of attempts for LMA insertion and ease of LMA placement [10].

- 1-no resistance
- 2-mild resistance
- 3- moderate resistance and
- 4- inability to place the device.

Confirmation of successful LMA insertion was done by assessing the ability to attain at least 7 mL/kg of tidal volume with a square wave capnogram.

Measurement of the oropharyngeal seal pressure was done by closing the expiratory valve and setting the fresh gas flow at 3 L/minute until equilibrium was seen on the pressure gauge (above 25 cmH_2O).

The position of the LMAs was determined by fibreopticscopy. Fibreoptic scope was used to assess the glottis visualisation score (Brimacombe score [11]):-

1. no cords seen but function adequate
2. cords with posterior epiglottis seen
3. cords plus anterior epiglottis seen, and
4. only cords seen.

The time of tracheal intubation was started when the tracheal tube was inserted into the LMA passage until the square wave capnogram was confirmed. A standard flexometallic tracheal tube of adequate size was utilised to perform intubation through the LMAs. The success rate of first attempt was noted. First intubation attempt and total time after second attempt if any, was noted. The endotracheal tube was not advanced forcefully to avoid trauma. The numbers of blind intubation attempts were not more than two. The device was removed based on the manufacturers recommendations after successful intubation with the help of a movable stylet as a stabilising rod. Failed intubation was defined when it was not successful even after two attempts and if during the removal of LMA, the tube was displaced. For failed intubation after second attempt, classical direct

laryngoscopy was used to intubate the trachea. Endotracheal tube was fixed and connected to breathing circuit for ventilation.

In all cases, anaesthesia was maintained using 66% nitrous oxide with 33% oxygen and intermittent maintenance of inj. vecuronium (0.01 mg/kg) and sevoflurane 2%. Continous monitoring of heart rate and blood pressure was done and recorded at predefined time intervals, i.e, baseline, before intubation,1 minute, 3 minutes, 5 minutes, 7 minutes, 10 minutes, postintubation. After 10 minutes, the surgery was allowed to start, to avoid interference of surgical stimulus with haemodynamic parameters. The tube was removed after meeting the standard extubation criteria at the end of the surgery. Complications like sore throat, blood staining on the device, bronchospasm, laryngospasm, vomiting were noted.

STATISTICAL ANALYSIS

Data was entered in Microsoft excel and analysed by using Statistical Package for the Social Sciences (SPSS) version 22.0. Appropriate test of significance were applied accordingly. Chi-square test for qualitative and Analysis of Variance (ANOVA) test for quantitative data. A p-value <0.05 was considered statistically significant.

RESULTS

All three groups were comparable with respect to age, weight and gender distribution. No statistically significant difference was found in between the groups [Table/Fig-2].

Parameters	Group A n (%)	Group B n (%)	Group F n (%)	p-value
Age (years) Mean±SD	35.8±15.0	32.71±12.59	38.7±14.7	0.136
Weight (kg) Mean±SD	59.04±7.68	59.2±8.40	61±6.1	0.385
Gender (n, %)				
Male (61)	19 (42.2%)	22 (48.8%)	20 (44.4%)	0.811
Female (74)	26 (57.7%)	23 (51.1%)	25 (55.5%)	0.811
Total	45 (100%)	45 (100%)	45 (100%)	0.811

[Table/Fig-2]: Demographic profile (N=135).
Test applied for age and weight: ANOVA test, Test applied for gender: Chi-square test

LMA insertion score of 1 was found to be better in group B (BlockBuster®) as compared to group A and group F. LMA insertion score of 3 was better in group A (Ambu® AuraGain™) as compared to group F and group B. However, all the three groups were comparable in terms of LMA insertion score of 2 [Table/Fig-3].

Score	Group A n (%)	Group B n (%)	Group F n (%)	p-value
1	7 (15.5%)	24 (53.3%)	19 (42.2%)	<0.001
2	22 (48.8%)	20 (44.4%)	25 (55.5%)	0.536
3	16 (35.5%)	1 (2.22%)	1 (2.22%)	<0.001
4	0	0	0	-

[Table/Fig-3]: LMA insertion score showing comparison between three groups.
Test applied: Chi-square test; A p-value <0.05 was considered statistically significant

Group B had a higher number of patients with a Brimacombe score 1 as compared to group A and group F (p-value=0.011). The results were found to be statistically significant. All three groups were comparable in having Brimacombe scores 2 and 3 [Table/Fig-4].

Group B had greater success rate of first attempt intubation in comparison with group F and group A. Overall success rate of intubation was 44 (97.7%) in group B, 39 (86.66%) in group F and 29 (64.4%) in group A [Table/Fig-5].

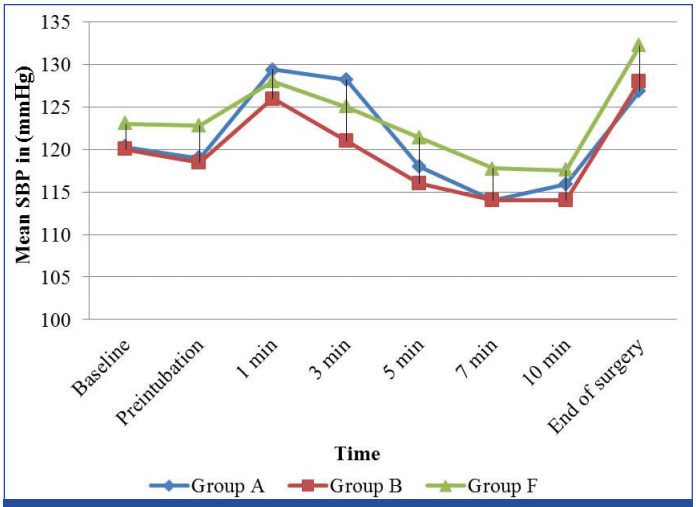
All the groups were comparable in respect of systolic and diastolic blood pressure, mean arterial blood pressure and heart rate per minute at baseline, pre intubation, 1, 3, 5, 7, 10 minutes postintubation and at the end of surgery [Table/Fig-6-9].

Score	Group A n (%)	Group B n (%)	Group F n (%)	p-value
1	3 (6.66%)	1 (2.22%)	9 (20%)	0.011
2	15 (33.3%)	18 (40%)	16 (35.5%)	0.799
3	12 (26.6%)	5 (11.1%)	14 (31.1%)	0.060
4	15 (33.3%)	21 (46.6%)	6 (13.3%)	0.002

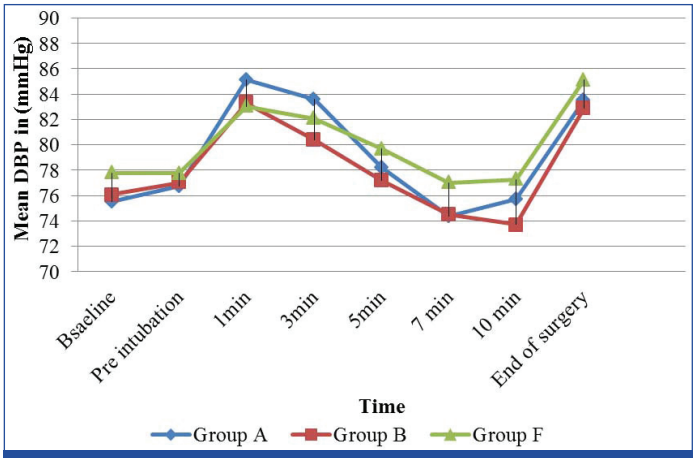
[Table/Fig-4]: Glottis visualisation score (Brimacombe score).
Test applied: Chi-square test

Number of attempts	Group A n (%)	Group B n (%)	Group F n (%)	p-value
1	10 (22.2%)	42 (93.3%)	29 (64.4%)	<0.001
2	19 (42.2%)	2 (4.44%)	10 (22.2%)	<0.001
Fail (>2)	16 (35.5%)	1 (2.22%)	6 (13.3%)	<0.001

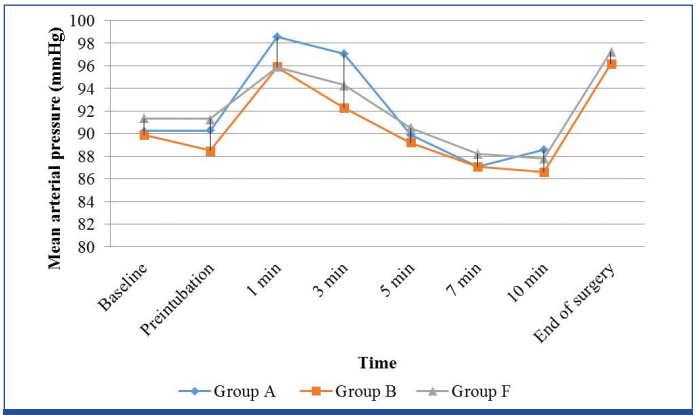
[Table/Fig-5]: Attempts of intubation.
Test applied: Chi-square test; For each group N=45; p-value <0.05 was considered statistically significant



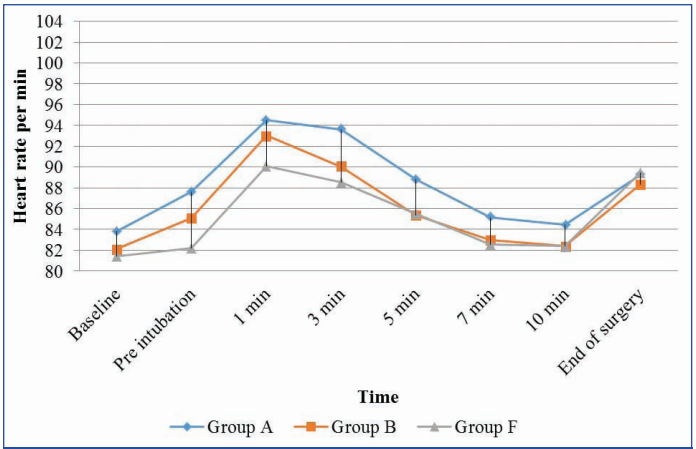
[Table/Fig-6]: Comparison of systolic blood pressure (mmHg) in three groups.



[Table/Fig-7]: Comparison of diastolic blood pressure (mmHg) in three groups.



[Table/Fig-8]: Comparison of mean arterial pressure (mmHg) in three groups.



[Table/Fig-9]: Comparison of heart rate in three groups.

All three groups were comparable in terms of incidence of sore throat as complication. However, other complications such as blood stained LMA and nausea/vomiting were least recorded in group B (BlockBuster®) as compared to other two groups [Table/Fig-10].

Complications	Group A n (%)	Group B n (%)	Group F n (%)	p-value
Blood stained LMA	7 (15.5%)	1 (2.22%)	9 (20%)	0.030
Sore throat	6 (13.34%)	3 (6.67%)	9 (20%)	0.177
Nausea/Vomiting	14 (31.12%)	5 (11.11%)	20 (44.44%)	0.002
No complications	18 (40%)	36 (80%)	07 (15.55%)	<0.001

[Table/Fig-10]: Comparison of the complications.
Test applied: Chi-square test; A p-value <0.05 was considered statistically significant

DISCUSSION

This clinical trial compared the performance and efficacy of the three LMAs in terms of first attempt success rate of intubation through the LMA, ease of LMA placement, duration of intubation through the LMA, glottis visualisation through LMA, oropharyngeal seal pressure, haemodynamic responses and incidence of any complication.

In the present study, the success rate of first attempt of intubation was higher in group B, as compared to group F and group A. These results were similar to study done by Endigeri A et al., in which the success rate of first attempt of intubation in group B (BlockBuster®) was higher as compared to group F (Fastrach®) [10].

In the present study, LMA BlockBuster® and LMA Fastrach® were found to be inserted with more ease as compared to Ambu® AuraGain™ GainR (BlockBuster®>Fastrach®>Ambu® AuraGain™). Endigeri A et al., also reported a similar ease with Blockbuster compared to Fastrach® [10].

Anatomic position of SAD was measured with the help of fibreoptic scoring and higher scores were related with an improved seal, reduced work of breathing and easier endotracheal intubation. The fibreoptic grading was found better in BlockBuster® and Ambu AuraGain® than Fastrach® LMA in the present study.

Similar results were found in the study by Anand L et al., where the fiberoptic grading was found to be better in Aura I as compared with FT LMA group [1]. Abdel Halim TM et al., who compared Air Q and FT LMA as conduit for fiberoptic intubation, also concluded that Air Q is an excellent conduit for fiberoptic tracheal intubation [12]. The absence of an epiglottic elevator bar is responsible for a better fiberoptic view in BlockBuster® and Ambu® AuraGain™. The group F LMA has an epiglottic elevating bar which can cause obstruction in fibreoptic view because of its centre position and to move the scope one side from the midline [8].

In the present study, the mean oropharyngeal seal pressure was greater in group A as compared to group B and group F. Similarly, in the study by Endigeri A et al., there was a significant difference in the oropharyngeal seal pressure between BlockBuster® LMA and Fastrach® LMA. It was 33.7±1.8 cm H_2O in group B and 22.7±1.5 cm H_2O in group F.

In the present study, the total duration of intubation was found to be lesser in group B as compared to group A and group F including first attempt and second attempts. In the study by Neoh EU and Choy YC, the time for intubation was lesser in group B (BlockBuster®) compared to group F (Fastrach®) [6]. In the study by Anand L et al., Fastrach® LMA required shorter mean time than Ambu® AuraGain™ for each of the first, second and third attempts at endotracheal intubation [1].

In the present study, blood stained LMA was significantly lesser in group B as compared to group A and group F. Similarly, there was a statistically significant lower incidence of nausea/vomiting postoperatively with group B. However, all three groups were comparable in terms of incidence of sore throat as a complication. In the study by Endigeri A et al., the supraglottic injury score or complication rates like sore throat and blood staining on LMA were significantly less with BlockBuster® as compared to Fastrach® [10]. However, incidence of nausea and vomiting were comparable between two groups. In the study by Anand L et al., no significant differences were found with respect to haemodynamics, incidence of sore throat, and visible blood on the device among the two groups (BlockBuster® and Fastrach®) [1].

Limitation(s)

The present study did not include emergency cases for airway management. Only elective cases were included in the study. Blinding could not be done as a result there could be bias in the study. Although, a standard scoring system was used for assessing ease of LMA insertion, but it is a subjective scale and hence, person to person variation might have occurred.

CONCLUSION(S)

The present study showed that there was an easy insertion of LMA BlockBuster®, easier than other two types of LMA (BlockBuster®>Fastrach®>Ambu® AuraGain™). Blockbuster LMA was found to be superior than Fastrach® LMA and Ambu® AuraGain™ in terms of first attempt successful intubation, time taken for intubation, glottis visualisation and had lesser incidence of complications like blood stained LMA and nausea/vomiting than Fastrach® LMA and Ambu® AuraGain™. All the three LMAs were suitable for oxygenation and ventilation. Hence, BlockBuster® LMA is a better conduit for tracheal intubation than Fastrach® LMA and Ambu® AuraGain™ in adult patients with no anticipated airway difficulties.

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